

The patient's voice as a game changer in regulation

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Chapter 1

General introduction

Background

In a number of countries such as the Netherlands, the UK and Australia, regulators of healthcare quality have been criticized after high-profile incidents such as the Bundaberg hospital scandal in Australia [1, 2], the Mid Staffordshire NHS Foundation Trust scandal [3, 4] in the UK and the ‘baby Jelmer’ case in the Netherlands (more information in the following paragraph) [5]. Governments are facing problems concerning organizational failures, public confidence in regulators and accountability of regulators, and society is calling for stricter supervision in cases where healthcare providers fail to comply with quality standards [6-8].

There are several factors underlying the problems that regulators face. Firstly, when information about the work of regulators becomes public, it often relates to cases where something went wrong. On the one hand, regulatory agencies interact with institutions, businesses and professionals rather than members of the public. Therefore, the public profile of regulatory agencies may be low and the general public may not find them very interesting [9, 10]. On the other hand, regulators tend to be more publicly visible in times of crisis [9, 11]. Scandals and incidents (and the media interest in them) may have endangered public confidence in healthcare and its regulation [6, 9]. Secondly, the criticisms focus on the policies of the regulators, who are thought to be responding too mildly to incidents and to healthcare providers who are not meeting standards. Those policies are not created by chance, but the underlying reasoning behind those policies is mostly based on the theory of ‘responsive regulation’ [12].

Thirdly, complaints by patients are an important topic of discussion; in a number of countries, there have been comments about regulators after patients reported that their complaints were being ignored and they were left frustrated [3, 4, 13-16]. However, in many cases it is not the regulator’s statutory task to handle complaints by individuals.

Nevertheless, evidence from a small body of research suggests that society has other views and expectations of the role of the regulator concerning health and safety risks than governments or healthcare professionals [9, 17]. There seems to be a discrepancy between the public’s and patients’ perspectives and that of the regulator. Simultaneously, regulators in various countries and different sectors have expressed greater commitment to involving the public and informing them more about their regulatory policies [8, 18-21].

This thesis therefore assesses the discrepancies and similarities between the values and expectations of the public and the theories, concepts and policies of

healthcare quality regulation, as well as what this implies for the alignment of the two perspectives. This knowledge is needed in order to effectively assess different approaches for involving the public in regulatory policies.

This general introduction addresses important theoretical concepts and ideas underlying regulation and its related issues, patient involvement and patients' complaints, followed by a description of healthcare quality regulation policies and related issues in the Netherlands. The goal, relevance, research questions and outline of this thesis will be addressed at the end of this chapter. First, though, the Dutch 'Baby Jelmer' case is described, the case that in particular was the main driving force for this study. This individual case reflects the problems concerning the Dutch regulator over the past few years, but is also comparable to other incidents in the Netherlands and elsewhere.

The Dutch 'Baby Jelmer' case

Baby Jelmer, the second of premature triplets, was born on 2 May 2007 in a Dutch hospital. He underwent surgery and permanent brain damage was diagnosed several days later. The hospital reported this, as a notifiable adverse event, to the Dutch Healthcare Inspectorate. As usual, the Inspectorate asked the hospital to investigate the event and inform the Inspectorate about the results. It took almost 6 months before the results came and the Inspectorate sent a reminder to the hospital. In November 2007, the report and results came. In December 2007, Jelmer's parents informed the Inspectorate of what had happened to their child in the hospital, because they had a large number of questions.

In January 2008, the Inspectorate decided to start its own investigation because there were too many ambiguities in the hospital's report. On 6 December 2010, more than 3.5 years after Jelmer's surgery, the Inspectorate issued a report. This report met with criticism from the hospital in question and the anaesthesiologists involved, though the parents agreed with it. The Inspectorate withdrew that report because it contained inaccuracies and replaced it on 14 July 2011 with a new report, without consulting Jelmer's parents. The parents disagreed with the second report.

The total time taken by the Inspectorate to handle this case since the notification in May 2007 was more than four years. A special commission was appointed to investigate the incident and the role of the Inspectorate in the case [22]. Furthermore, two other commissions were appointed to investigate the methods of the Inspectorate with respect to reports by members of the public and

the internal organization of the Inspectorate. The commissions all concluded that the lead times for handling reports from the general public were too long and that the Inspectorate lacked empathy towards the public. Furthermore, they concluded that there are uncertainties about the role of the Inspectorate with regard to reports by members of the public [13, 23].

Jelmer's parents also contacted the National Ombudsman. In cooperation with a national TV programme, the Ombudsman called for people to report their experiences with the Inspectorate, which resulted in a list of 334 complaints from the public and national media exposure. The conclusions were that the Inspectorate did not take patients and their complaints serious enough, and was too reticent in taking actions. The Ombudsman stated that there is a discrepancy between the (limited) interpretation of the Inspectorate's task and the image that the public have of the Inspectorate [16].

However, those criticisms were not shared by everyone. The Inspectorate claimed that it is not its task to handle complaints by individual patients, unless the problems are structural or very severe and the question was raised of whether it is desirable that the Inspectorate should take on that role.

Nevertheless, the Inspectorate and political circles initiated several efforts towards improvement. The Inspectorate's policies were re-examined and an advice point for members of the public with complaints about healthcare was set up [24].

Theories, concepts and policies of regulation

The emergence of state regulation

As described earlier, exposure of regulators is often related to incidents. The focus on incidents and the state regulator's role has grown over recent decades.

Classical studies on risk management and risk perceptions of society describe the development of a risk society [25, 26]. New or 'modern' threats are a result of the nature of our society; they are not external threats, but the threats are a product of our actions or our social systems, being problems that are produced within the society. Whereas many (natural) hazards that previously threatened people have largely been averted, people are not going to feel safer, partly because of the growing attention paid to incidents in society and the media.

The management of risks in society is an important issue in many western countries. In the nineteenth century, on recognizing that some risks could only be fought collectively, governments gained a greater role when damage occurred. In

this precautionary culture, it was seen as the task of government and politics to identify social risks and to take measures [27].

Over the last few years, there have been ongoing debates about the assumption that the government should cover all risks and the related tendency (in the case of incidents) to start by looking for someone to blame [28]. Also in the media and in political debates, there is not only a great deal of attention paid to the occurrence of incidents, but especially to the question of who is (legally) responsible for the incident or should be called to account. In addition to addressing the immediate cause (e.g. producer or supplier), the role of the public regulator is under the microscope, where the focus on the responsibility of the origin and prevention of risks is shifting from the supervised party to the state regulator. In other words, the regulator is not only seen as a referee of guilt and penalty assessment, but also as a subject of investigation. Attention is moving from the proprietor or person responsible for the whatever went wrong to the inspector who should or could see and prevent it [29,30]. This also could mean that regulators will increasingly have to be transparent and account for their work [31].

In healthcare, the idea that the state has an important role in monitoring the quality of care was also not always obvious. In the past, healthcare was regulated predominantly by professional self-regulation [32], for instance referring to the Hippocratic oath. The thinking about changing risks meant that risks were not considered and addressed from a professional context, but increasingly from a management and governance one [30], shifting from prevention towards proactive risk thinking and from criminal justice towards administrative governance [33]. In addition, medical scandals in the UK, Australia and New Zealand from the 1990s contributed to ending medical professionals' long-standing model of self-regulation by their peers and encouraged the shift towards external or state regulation [34, 35].

Governmental regulation: responsive regulation

Regulators are often criticized for their soft approach and their reliance on the regulated party's ability to make improvements. However, the decisions regulators make are not determined by chance. There are several assumptions that underlie those policies.

Because of limited capacity and scarce resources, more flexible and responsive ways of regulation were sought [6]. Therefore, internationally, regulation in various

industries such as healthcare, finance and the environment is based on the theory of 'responsive regulation' from Ayres and Braithwaite (1992) [12, 36]. Although other academics have developed other theories, this theory is still the most influential [37].

The basic idea is that the parties being regulated are considered to be trustworthy and intrinsically motivated by social responsibility. The mere presence of a regulator can already have effects and compliance is more efficiently enhanced by cooperation and gentle persuasion instead of harsh sanctions. According to the theory, strategies of regulation should be flexible, in synergy with the context of those being regulated, and based on dialogue. Regulation based on trust will improve quality of care more effectively, whereas regulation based on distrust arguably only leads to more sanctions and therefore more demand on the regulator's capacities and ultimately to higher costs to society [12]. Single regulatory strategies are seldom effective. Weaknesses of one strategy can be complemented by the strengths of another. A wide array of strategies such as monitoring performance indicators and targets, incident reporting systems, and more strict measures such as criminal penalties should together contribute to the effectiveness of regulation [12, 38]. Regulatory compliance is encouraged by using cooperation, persuasion, inspection and enforcement notices in the first instance, and secondarily by applying heavier measures in the case of riskier behaviour. This vision is often described as 'high trust, high penalty' [12]. This strategy corresponds to the international trend of government functions changing from the old 'commanding and controlling' to 'steering not rowing', where responsibilities are shifted from the government to the field and new governing mechanisms are introduced such as marketization of public sectors [6, 32, 39-42].

However, calls are being heard from political circles and society - often after incidents - and through the influence of the media, for a more punitive or vertical style of regulation than the responsive or cooperative style. The attention paid to regulation increases when incidents occur. Budget cuts, deregulation and marketization are embraced when everything goes well, but when things go wrong, there are calls for more and stricter regulation. This is also known as 'the regulation paradox' [29].

Making a choice somewhere on the continuum between the two control style 'extremes' fits with the 'high trust, high penalty' idea of responsive regulation, for which the approach selected depends on the situation. The choice of approach by

the regulator is then a question of proportionality and the situation; balancing between different approaches of regulation.

Tripartism

Another important component of the theory of responsive regulation is ‘tripartism’, which is proposed as a mechanism for empowering public interest groups and decreasing the risk of regulatory capture. Capture is a form of political corruption that occurs when a regulatory agency acts in the interest of the regulated party instead of the public’s interest. Furthermore, tripartism is thought to prevent conflicts of values between the different stakeholders.

In tripartism, a public interest group participates as a third group in the regulatory process: it is given power by being granted access to all the information that is available to the regulator, and by being offered a seat at the negotiating table for enforcement and compliance [8, 12, 14, 43-45]. It is also seen as a democratic way of regulation by giving the public a voice. In addition, there are merits not only for the public, but also because it is considered to be a strategy for implementing laws and regulations that have already been defined. Under tripartism, public interest groups could add substantially to the capacity of regulators to monitor outcomes. The eyes and ears available for verification are multiplied. If tripartism succeeds in building trust and honest communication, all players will be better able to recognize what the others (for instance regulator and regulated party) are doing and when they are cooperating [46]. In many countries, involvement of the public in regulation is on the policy agenda [38, 47-50]. These developments can also be seen in the light of a larger trend of democratization in healthcare as described in the following paragraphs.

Democratization in healthcare

In regulatory policies, as well as in the broader arena of healthcare, it is becoming more and more widely recognized that patients should have a more distinct role in the system.

In Western countries, healthcare systems have been changing rapidly over the last decades. Healthcare is the particular area where changes, reforms and new technologies are implemented. Challenges of an aging society and rising costs lead to institutional changes in healthcare systems such as the introduction of competition mechanisms. The market is supposed to be a new governing

mechanism [40, 41, 51].

Those reforms in healthcare systems that are ongoing worldwide demand changes to the roles of the actors, including patients. Governments aim to develop policies and legislation to strengthen people's rights as part of the emancipatory developments in large parts of Europe and the USA to empower various groups within society, e.g. women, homosexuals and patients [52]. Patient participation and active patient choice are thus promoted [32, 39].

In the new systems, patients are encouraged to choose their care providers and 'vote with their feet'. This selection process will encourage providers to compete for patients by improving their quality and decreasing their costs, which eventually helps ensure the quality, efficiency and equity of healthcare [53]. For patients to be able to actively choose the best provider, they need to be informed about the quality of providers. This means that quality information needs to be transparent. Insurers, care providers and regulators too are expected to play a role in contributing to this transparency [39]. Transparency however has both positive and negative consequences. Transparency may encourage confidence in the care on the part of the public, because it provides insights into the level of quality of healthcare. On the other hand, maximum transparency about problems in healthcare may mean that a more negative picture than necessary of care may be drawn and a negative picture of regulators may emerge. This is also called the 'information paradox': the more visible the work of the regulator, the greater the extent to which abuses and incidents get publicity [54]. Nevertheless, partly due to the Internet and new technologies such as health apps on smartphones, patients are getting more and more access to information about the quality of care, as well as more access to their own health information than ever before, putting them more and more in the driver's seat.

Other forms of democratization in healthcare at the macro or micro level are the contribution of patients in decision-making processes at national and local levels, including developing guidelines or policies and setting research agendas, as well as regulating and improving the quality of care [8]. The latter will be described in more detail below.

Democratization in healthcare quality regulation

Following the developments described above, it has been argued in several studies that patients and their experiences and complaints have been largely ignored in patient safety management [55-58]. Current patient safety approaches possibly

tend to reflect a narrowly clinical perspective that excludes non-clinical or non-disease-specific aspects of care that patients find important [57-62].

Regulators of healthcare quality in various countries are struggling with criticisms, often articulated by the media, for not taking patients and their complaints and information seriously [4, 8, 16, 63]. Public participation in healthcare quality regulation may be a solution for helping regulators overcome those criticisms, meet society's needs and expectations, and enhance their public accountability [8, 12, 14, 43-45, 49].

Furthermore, it has been stated that patients can add value to safety management by providing 'soft intelligence', information about blind spots that care providers are unaware of [7]. It has also been shown that patients, especially those who suffered harm, are not only able but also in a very good position to observe their safety and identify contributory factors [64]. In addition, the value that information extracted from patients' complaints adds to other sources of information about healthcare quality has been proven in other research. It was shown that different reporting systems such as incident reporting, patient complaints and malpractice claims all produce substantially different, incomplete but complementary, pictures of patient safety. Moreover, the traditional monitoring system (clinical adverse event reporting) only represents a small part of the picture. Underreporting is a major issue, as sometimes 95% of the adverse events are not reported [65].

For those reasons, public participation in regulation is an important item on the policy agenda in several European countries [21, 50, 66, 67]. However, little is yet known about what the best ways are for involving patients in the regulation of healthcare quality.

Approaches for including patients

There are various approaches for including patients in regulation policies, such as using patient satisfaction surveys (the traditional method) or newer approaches such as searching for patients' comments on social media [68-71].

Generally, patient satisfaction surveys such as Consumer Quality Indices (CQI) are used for incorporating the patients' perspective in regulation policies. A strong point of surveys is that a large group of patients can be reached.

Social media (including Facebook, Twitter and rating sites) have been shown to be a promising source of information complementing traditional information sources and providing unique insights into healthcare quality [68, 70, 71]. Large

amounts of comments can be found on social media. For instance, on Twitter, an average of 500 million tweets are sent a day [72]. A wide variety of topics in healthcare are discussed on Twitter, such as experiences with staff, processes and facilities. Most of the comments are positive, so it provides a mechanism for positive feedback to healthcare staff and demonstrates good performance by providers [71]. Furthermore, research has shown that high ratings for care institutions on Yelp were statistically significantly correlated with lower mortality for myocardial infarction (MI) and pneumonia, and fewer readmissions [73]. Other research has shown that searching on Yelp also reveals novel themes that are not included in surveys [74]. Another new way to strengthen the patients' perspective that is still in an experimental phase is to involve them as 'mystery guests' during inspections and regulatory visits to care providers [8, 18].

Patients' complaints

Another way to include patients in regulatory policies is via their complaints. As described, the way regulators deal with patients' complaints is an important point of discussion and the main reason for this study. Including patients and their complaints in regulatory policies can be seen as a form of participation. Patients may have the option of reporting their information about healthcare to regulators by filing complaints (if the regulator has set up a complaints' desk). There are however differences between countries in what role patients' complaints currently have in healthcare quality regulation. In Finland for example, patients can file complaints with the healthcare quality regulator, which then judges the legitimacy of the complaint [75, 76], while in other countries such as the UK, Australia and the Netherlands, individual complaint handling is not the primary task of the regulator. Signals derived from individual complaints are often used to monitor the performance of individual care providers [8, 20, 63]. Nevertheless, research has shown that most patients who lodge complaints with various complaints bodies expect the same of the procedure. They want something to change as a result of their complaint. However, they often think that nothing has changed as a result of their complaint [63, 77-83].

In this study, patients with complaints, their expectations and experiences, and the regulator's responses to them are used to gain more understanding about the patients' and regulator's perspectives. Complaints are a form of 'voice' that fits within the idea of public participation and democratization in healthcare. Studying this could generate information about what it would mean and what is needed for

regulators if they want to involve patients in their work. Furthermore, it could help regulators improve their responses to complainants, as that was what they were originally criticized for. It could point out more specifically where the problems lie. To summarize, there are a number of possibilities – not limited to the ones described – for including patients in regulatory policies. However, patient participation in regulation is not self-evident and it goes hand in hand with several dilemmas and bottlenecks. This thesis aims to contribute to this discussion and to improve the relationship between patients and regulators by studying the patients' perspective and assessing it against regulatory perspectives.

The Dutch situation

The studies in this thesis have been carried out within the Netherlands. The Dutch situation regarding regulation of healthcare quality will therefore be described below.

In the Netherlands, regulation of healthcare quality is carried out by the Dutch Healthcare Inspectorate (IGZ).

Since 1996, the Care Institutions Quality Act (KWZ) has stipulated that the responsibility for quality of care lies primarily with the care provider. This includes ensuring that healthcare providers give the patients the right to complain. The idea behind the law was that "Quality of care [...] is not so much the product of the requirements the law imposes on a provider but of the way the latter has shaped the care process [84]." The objective is that the standards for 'responsible care' are defined and developed by the professional field. Healthcare providers are expected to establish quality systems that monitor quality performance and send this information to the Inspectorate. The Inspectorate assumes that care providers have the intrinsic motivation to do this properly, based on the principle of 'high trust, high penalty' from the theory of responsive regulation. The choice of imposing measures is based on the severity of the problem and the attitude of the care provider [54].

Responsiveness, i.e. the extent to which the Inspectorate succeeds in anticipating to the healthcare practice that it supervises, plays an important role in the effectiveness of regulation. This responsiveness is necessary as the decisions and measures taken by the inspectors must be incorporated into the local care practices if they are to lead to improvement [85]. This responsiveness is also possible because most inspectors (at the time of the study) came from the field

that they supervise. Inspectors at the IGZ have worked for an average of 12 years in an executive, management or scientific position in healthcare before joining the IGZ [86, 87]. There could therefore be a question of whether the professional perspective dominates within the Inspectorate's work.

Complaints and regulation in the Netherlands

From a statutory perspective, the Dutch regulator has no immediate task regarding complaints and problems of individual patients and members of the public. The Inspectorate handles complaints only when there is a serious threat to the health or safety of the patient or when the complaint indicates a structural problem [88]. At the time of this study, the Inspectorate supervised compliance with the Clients' Right to Complain Act, which requires care providers to have an easily accessible complaints facility for patients. That task is primarily administrative in nature and thus not aimed at satisfaction of individual members of the public. However, the past few years have shown that society and politics have other expectations than the Inspectorate could fulfil, as is shown in the Baby Jelmer case [16, 55, 89, 90]. The case also shows the Inspectorate's struggle in meeting those expectations while at the same time carrying out its statutory task.

In addition, the Inspectorate has repeatedly had negative coverage in the media, and there was criticism of the actions taken by the Inspectorate [22, 91-94]. Sometimes the Inspectorate was accused of too much reliance on the ability of the care provider in question to resolve its own issues, which was again the case with Baby Jelmer [5, 15, 16].

In 2001, the advisory group Abeln gave the recommendation that the Inspectorate should be positioned as an organization "of the Minister, focusing on providers, but mainly acting in the interests of the public, for the public" [94]. During the years that followed, while several other incidents occurred in which the Inspectorate's role was criticized, the Minister urged the Inspectorate to make improvements in this area. In 2012, the Minister decided to start a contact point for complaints where patients can go with their complaints that can provide them advice about other options for their complaint [24]. In its latest policy plan for 2016-2019, the Inspectorate planned to give the public a greater role in its policies. Another important priority is public transparency about its own work [19]. Furthermore, a new law concerning quality of care and complaints handling (Wkkgz) is being introduced in the year of writing (2016), aiming to improve patients' satisfaction with complaint handling.

Goal, relevance and outline of this thesis

Little research has been performed into society's views and expectations of the regulation of quality of care. The aim of this study is to use the developments described to uncover potential discrepancies between legislation and policy and the views and expectations of the general public on regulation of quality of healthcare. Furthermore, the views, expectations and experiences of patients with complaints aimed at the Inspectorate are explored and a tool is developed for systematically analysing and using complaints for regulatory purposes. The overall goal is to improve the alignment of the perspectives of the patients and the regulators, and to assist regulators in responding to, involving and using patients and their information within their policies. The challenge is to effectively define the relationship between the regulator and patients.

This research was carried out within the Academic Collaborative Centre on Supervision, where researchers from four research institutes cooperate with the Inspectorate. This gives the Inspectorate the possibility of proposing research questions that occur in its own practice. The problem that is investigated in this study is a societal problem that cannot be classified exclusively in a single specific research area. Furthermore, this study was affected by various political and societal movements which therefore demanded a pragmatic and dynamic approach in which the actual steps to be taken were not established beforehand. This allowed the study to support regulation in practice but also contribute to the scientific body of evidence.

Research questions

We formulated the following research questions:

Research question	Chapter
What are the similarities and discrepancies between the public's/patients' perspectives and the regulator's perspective?	2, 6
What are the implications for incorporating the patients' perspective in the inspectorate's work, and what are the advantages and disadvantages?	6,7
What are the implications for improving the responses of regulators to patients and their complaints and how can regulators make effective use of complaints?	3, 4, 5

This thesis is divided into 7 chapters:

1. Introduction

2. The public's voice about healthcare quality regulation policies. A population-based survey.

The aim of this study was to explore possible discrepancies between public values and opinions and current healthcare quality regulation policies.

3. Patients' perspectives on the role of their complaints in the regulatory process.

This study explores what patients who made complaints expect to achieve in the process of healthcare quality regulation.

4. Including patients' complaints in healthcare quality regulation systems: testing the reliability of a taxonomy.

We aimed to provide a taxonomy for healthcare quality regulators for encoding complaints, and to empirically test that taxonomy to determine its reliability.

5. Classifying patients' complaints for regulatory purposes: a pilot study

This study seeks an answer to the questions of what information can be extracted by analysing patients' complaints about all healthcare sectors received by the regulator and what can be learned from this from a regulatory perspective.

6. Is there a mismatch between the perspectives of patients and regulators on healthcare quality? A survey study

Patient's complaints often involve non-clinical subjects such as communication or organizational problems, while regulators evaluate complaints based on clinical standards. This study examines whether patients' expectations of and experiences with reporting their complaint to the regulator are influenced by the subject their complaint is about.

7. General discussion

Data collection

A questionnaire was submitted to 1500 members of the Dutch Healthcare Consumer Panel. This panel is representative of the Dutch general population in terms of age and gender. Questions were developed around central ideas underlying healthcare quality regulation policies.

Interviews were conducted with 11 people who had submitted a complaint to the

Dutch Healthcare Inspectorate. Based on the interview results, a second questionnaire was sent to 343 people who had submitted a complaint to the Inspectorate between August 2012 and November 2012 and 653 people who had submitted a complaint between April and August 2013. An existing taxonomy for the analysis of complaints in healthcare was developed further into a taxonomy that is applicable to a wide array of healthcare sectors and for use by healthcare quality regulators. Various statistical analyses were carried out using the data.

Outline of this thesis

After this general introduction, Chapter 2 provides an exploration of the opinions and expectations of the general Dutch public of regulation of healthcare quality. The chapters that follow then focus on patients who reported complaints to the regulator. Chapter 3 is an exploration of the expectations and experiences of patients with complaints who turned to the regulator. Chapters 4 and 5 concern the utilization of complaints for regulatory purposes. A taxonomy was developed and tested for its reliability, and it is explored what information complaints provide on an aggregated level. Finally, Chapter 6 investigates if the perspectives of regulators and patients mismatch and how this can be addressed.

The results of the study are summarised and discussed in view of earlier findings, theory and methods in Chapter 7. In addition, implications for practice and further research are formulated.

This thesis is based on five articles about the studies performed. Some overlap between the chapters is inevitable as every chapter was written to be read as a stand-alone article in its own right.

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Chapter 2

The public's voice about healthcare quality regulation policies. A population-based survey

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Abstract

Background

In the wake of various high-profile incidents in a number of countries, regulators of healthcare quality have been criticised for their 'soft' approach. In politics, concerns were expressed about public confidence. It was claimed that there are discrepancies between public opinions related to values and the values guiding regulation policies. Although the general public are final clients of regulators' work, their opinion has only been discussed in research to a limited extent.

The aim of this study is to explore possible discrepancies between public values and opinions and current healthcare quality regulation policies.

Methods

A questionnaire was submitted to 1500 members of the Dutch Healthcare Consumer Panel. Questions were developed around central ideas underlying healthcare quality regulation policies.

Results

The response rate was 58.3 %. The regulator was seen as being more responsible for quality of care than care providers. Patients were rated as having the least responsibility. Similar patterns were observed for the food service industry and the education sector. Complaints by patients' associations were seen as an important source of information for quality regulation, while fewer respondents trusted information delivered by care providers. However, respondents supported the regulator's imposition of lighter measures firstly.

Conclusions

There are discrepancies and similarities between public opinion and regulation policies. The discrepancies correspond to fundamental concepts; decentralisation of responsibilities is not what the public wants. There is little confidence in the regulator's use of information obtained by care providers' internal monitoring, while a larger role is seen for complaints of patient organisations. This discrepancy seems not to exist regarding the regulator's approach of imposing measures. A gradual, and often soft approach, is favoured by the majority of the public in spite of the criticism that is voiced in the media regarding this approach. Our study contributes to the limited knowledge of public opinion on government regulation

policies. This knowledge is needed in order to effectively assess different approaches to involve the public in regulation policies.

Background

In the wake of various high-profile incidents such as the Mid Staffordshire NHS Foundation Trust scandal in the United Kingdom, several countries including the Netherlands have faced comparable organisational crises and problems with achieving political goals such as public confidence in healthcare, legitimacy and accountability of regulators in healthcare [1–7]. The criticisms expressed in the media, by politicians and by patient organisations are often directed at the regulators' cooperating approach in cases where healthcare providers fail to comply with quality standards. Furthermore, it is claimed that regulators fail to respond to patients' complaints [4, 7].

Although it is often recommended to involve the public as they are the final clients of the regulator's services [8, 9], their opinions on regulatory policies have only been discussed in research to a limited extent. The main research question in this study is therefore whether there are discrepancies between the values and opinions of the public and the current values of policies and strategies for regulation of healthcare quality, and if so, what are these discrepancies? The Dutch situation is used as a case study.

The next paragraph addresses important theoretical concepts underlying regulation, followed by a description of healthcare quality regulation policies and related issues in the Netherlands. We then explain the methods used in this study, followed by the results and discussion.

Responsive regulation

Internationally, regulation in various industries such as healthcare, finance and environmental businesses is based on the theory of 'responsive regulation' of Ayres and Braithwaite (1992) [10, 11]. The basic idea is that the parties being regulated are considered to be trustworthy and intrinsically motivated by social responsibility. According to this theory, strategies of regulation should be flexible, in synergy with the context of those being regulated, and based on dialogue. Regulation based on trust will improve quality of care more effectively, while regulation based on distrust arguably only leads to more sanctions and therefore

more capacity on the part of the regulator and ultimately to higher costs to society [10]. Single regulatory strategies are seldom effective. Weaknesses of one strategy can be complemented by strengths of another. A wide array of strategies such as monitoring performance indicators and targets, incident reporting systems, and more stricter measures as criminal penalties should together contribute to the effectiveness of regulation [10, 12]. Regulatory compliance is encouraged by using cooperation, persuasion, inspection and enforcement notices in the first instance, and secondarily by applying heavier measures in the case of riskier behaviour. This vision is often described as ‘high trust, high penalty’ [10]. This strategy corresponds to the international trend of government functions changing from the old “commanding and controlling” to “steering not rowing”, whereby responsibilities are shifted from the government to the field and new governing mechanisms are introduced such as marketisation of public sectors [4, 13–17].

Another important component of the theory is ‘tripartism’, which is proposed as a mechanism for empowering public interest groups and decreasing the risk of regulatory capture. Furthermore, tripartism can prevent conflicts of values between the different stakeholders. In tripartism, a public interest group participates as a third group in the regulatory process: it is given power by being granted access to all the information that is available to the regulator, and by being offered a seat at the negotiation table for enforcement and compliance [3, 10, 18–21]. In many countries, involvement of the public in regulation is on the policy agenda and different approaches are being considered, such as using the experiences of the public at large [5, 12, 22–24].

However, research has shown that public interest in regulatory agencies is limited, as is the public visibility of these agencies [25–27]. Low public interest may not be a great problem, as these agencies interact primarily with the industry rather than with the general public. However, regulators often do tend to become visible to the public in times of crisis [27, 28]. Scandals and incidents and the accompanying media attention can have a direct influence on the regulators’ reputation [28–30], and may possibly jeopardise public confidence in the industry and its regulation [4, 7, 31]. Although regulation is often defined as “sustained and focused control exercised by a public agency over activities that are valued by a community” [32, 33], research shows that in risk cases involving for instance genetically modified food or radioactive waste, the public does not regard the government regulator as

having the same values as themselves [34]. This also implies that it is important for ensuring the legitimacy, public accountability and transparency of a regulator and for involving the public in regulation policies that the values of regulatory policies are consistent with the values of communities. Differences between the values and opinions of the public and the current values of policies and strategies for regulation and underlying ideas of the theory of 'responsive regulation', are the main focus of this article.

Dutch healthcare quality regulation policies

In the Netherlands, the healthcare system was reformed into a regulated market system in 2006 [35]. Before the introduction of this reform, two types of healthcare quality regulation could be distinguished: state regulation and professional self-regulation. Since the competition mechanisms were introduced, the market was supposed to be a new complementary governing mechanism and the state's function followed a more decentralised approach [17, 35, 36]. In this system, the focus on patient choice and transparency of quality of care has increased [13, 15–17].

Since the introduction of the Quality Act (1996), care providers have been given more responsibilities and are supposed to develop quality standards. The Dutch Healthcare Inspectorate monitors performance against these standards (more information about monitoring and enforcement strategies in Table 1). However, the Netherlands has also seen several high-profile incidents in healthcare that led to concerns in society and a heated political debate about the Inspectorate [18, 36–39]. It was argued that the Inspectorate failed to respond to emerging signals including patients' complaints and it should have enforced the rules more strictly, because its actions had been too hesitant and trusting of care providers who were not complying with quality standards. Members of the Dutch House of Representatives spoke of "the debate representing the gap between the public and politics, but in miniature". It was stated that the public and their complaints deserve more attention and should be involved in regulation policies [40]. In the Netherlands, those problems regulators experience are not unique to the healthcare sector. State regulators in the food service industry and education sector face similar incidents and reputational losses [41]. Therefore, this article aims to provide a broader picture of public values and opinions about state agencies and their role in risk regulation.

Table 1 Regulation and enforcement instruments of the Dutch Healthcare Inspectorate

In the Netherlands, the Dutch Healthcare Inspectorate is the body appointed by the government to supervise and regulate quality of healthcare. It is an independent part of the Ministry of Health, Welfare and Sports. The Inspectorate pays regular visits, which become more frequent if care providers do not comply with quality standards. Both care providers and the public can report incidents or lodge complaints. However, the Inspectorate's statutory tasks mean that it cannot handle complaints by individual patients unless the complaints are structural or very severe

Information about the quality of care is collected and analysed to signal potential risks. Information sources include the following:

- System based supervision (monitoring of internal quality systems and governance arrangements)
- Performance indicators
- Reporting of incidents (by the public or care providers)
- Detection of prosecutable facts
- Thematic supervision

The Inspectorate is authorised to use the following regulation and enforcement instruments:

- Advice and incentives (consultation, campaigns);
- Corrective measures (impose improvement plans, strengthened monitoring);
- Administrative measures (command, advice to the Minister to issue a direction, penal sum, administrative fine);
- Measures under criminal or disciplinary law.

Methods

Questionnaire

We developed questions reflecting the concepts of the theory of 'responsive regulation', 'high trust, high penalty', and 'tripartism'.

Firstly, in order to explore public opinion about the concept of 'responsive regulation' and the role and position of the state regulator with respect to the regulated parties and other stakeholders, we developed questions about the responsibilities of professionals, the government and other quality-of-care stakeholders. We included equivalent questions concerning quality regulation in the food service industry and in education, in order to assess whether public

opinion is unique to the health sector or if it represents more common attitudes regarding responsibility. The Dutch Inspectorate of Education is part of the Ministry of Education, Culture and Science.

The Netherlands Food and Consumer Product Safety Authority is part of the Ministry of Economic Affairs. They also base their regulation policies on the theory of 'responsive regulation' [42, 43].

In each sector, seven stakeholders were represented: the state regulators (Dutch Healthcare Inspectorate, Dutch Inspectorate of Education, Netherlands Food and Consumer Product Safety Authority); users (patients, students and their parents, and consumers); executive roles (care providers, teachers, and personnel who prepare food); direct colleagues of the executive roles in the three sectors; managers in the three sectors; ministers (Minister of Health, Welfare and Sports, Minister of Education, Culture and Science, Minister of Economic Affairs); and the European Union. For each stakeholder, respondents were asked to select an answer on a five-point scale, where one meant no responsibility and five meant full responsibility.

The other questions focused mainly on regulation of quality of healthcare by the Dutch Healthcare Inspectorate. The concept of 'tripartism' was explored by enquiring about the patients' responsibility for quality of care and the role patient information should have in monitoring healthcare quality. The questions also included existing information sources used by the Inspectorate, such as complaints from members of the public, complaints from care providers, and quality information supplied by the care providers themselves. In addition, sources for collecting information that are currently not used by the Inspectorate were included, such as searching the Internet for complaints.

Furthermore, the concept 'high trust, high penalty' was operationalised into questions focusing on what respondents considered to be good methods for regulating the quality of care. Respondents were asked what sanctions the Inspectorate should impose when care providers fail to provide adequate quality of care. Possible sanctions ranged from soft measures such as 'double-checking the care institution' to stricter measures such as 'closing the care institution'. Possible answers were 'totally disagree', 'disagree', 'neither disagree nor agree', 'agree' and 'totally agree'. The questionnaire was assessed by a permanent committee with delegates from several stakeholder organisations in healthcare such as of the Ministry of Health, Welfare and Sports, the Healthcare Insurers Board, and the Federation of Patients and Consumer Organisations. Their feedback was used to

finalize the questionnaire.

Panel

The questionnaire was submitted in February 2013 to a sample of 1500 members of the Dutch Healthcare Consumer Panel. The Dutch Healthcare Consumer Panel at that time consisted of approximately 6000 people aged 18 and older. A sample of 1500 persons that is representative of the Dutch population was drawn from the Healthcare Consumer Panel. The composition of the sample was compared with the general population in the Netherlands based on data from Statistics Netherlands [44], in order to make it reflect the composition of the Dutch population. Membership of the panel lasts for a maximum of 5 years. Members can quit at any time. New panel members are sampled from the general population and selected on basic characteristics needed to keep the panel representative for the Dutch population. This renewal also ensures that members do not develop specific knowledge of healthcare issues and that questionnaire fatigue does not occur. Questionnaires can be received by post or through the Internet, based on the preference of the member. To increase the response rate, two electronic reminders and one postal reminder were sent to members who had not responded yet. The Dutch Healthcare Consumer Panel is registered with the Dutch Data Protection Authority (no. 1262949) [45].

Ethics statement

Our study complied with the Helsinki Declaration where applicable. According to the Dutch 'Medical Research involving human subjects Act', neither obtaining informed consent nor formal ethical approval for this study was required [46]. No medical interventions were involved and the impact of the questionnaires on daily life was considered minor and thus the welfare and rights of the panel members were protected. Panel members were free to answer the questions or not.

Statistical analyses

In order to obtain a ranking of responsibility of the seven stakeholders in the three sectors, mean scores for responsibility were calculated. For each sector (healthcare, education and food service) respondents could rate responsibility on a five-point scale for each of the seven stakeholders. Differences between responsibility scores of groups of stakeholders were analysed by creating pair-wise comparisons using the Wilcoxon signed rank test [47].

For the other questions, about information sources and methods of regulation, the first two and last two answer categories were combined. Those results are presented descriptively.

Background characteristics of the study sample were compared to the characteristics of the Dutch population. Data on the Dutch population was obtained from Statistics Netherlands. Research on consumer behaviour shows that younger and more highly educated respondents have more critical attitudes towards services [48]. Therefore, differences in age categories, education levels and the extent to which respondents knew about the Inspectorate were therefore tested by chi-squared tests. This was not possible for ethnicity because almost all respondents were from Dutch origin.

P-values of <0.05 were considered to be significant. The data was analysed using the statistical software program STATA version 12.1.

Results

In total, 875 respondents returned the questionnaire (response rate: 58.3 %). Almost half of the respondents were female (47.7 %). They ranged in age from 18 to 87, with a mean of 51.4. More than half (57.6 %) of the respondents had a medium level of education. The study sample is ethnically less diverse than the overall Dutch population. See Table 2 for the study sample characteristics compared to the characteristics of the general Dutch population. With the exception of educational level and ethnicity, the sample is comparable to the Dutch population.

The majority (76.3 %) of the respondents of the Dutch Consumer Panel reported some degree of knowledge of the Inspectorate's work, and about one in ten respondents indicated that they knew exactly what the Inspectorate does. The remaining 14.6 % admitted a lack of knowledge. Additional analysis showed that respondents who are currently working or previously worked in healthcare (30.2 %) were significantly more likely to report knowing, either to some extent or very precisely, what the Inspectorate does.

Respondents rated the Inspectorate to bear most responsibility for the quality of healthcare, assigning it a significantly higher score than care providers (Table 3). Next in ranking came the care providers, the minister, managers, colleagues of care providers, and finally the European Union. Patients were rated to bear the least

responsibility for quality of healthcare, and this result was statistically significant. The same applies for students and their parents in the educational setting and consumers in the food service industry. The education sector showed approximately the same order of responsibility of stakeholders as healthcare, except for the positions of the managers and the minister being reversed. Significant differences were found between the Dutch Inspectorate of Education and teachers, but not between teachers and managers. In the food service industry, both the personnel who prepared food and the food sector managers were rated as bearing slightly more responsibility than the Netherlands Food and Consumer Product Safety Authority. However, this was not significant.

Table 2 Background characteristics of study sample and Dutch population^a

	Number	Study sample %	Dutch population (18 and older) 2013 %
Gender	874		
Female	416	47.6 %	50.5 %
Male	458	52.4 %	49.5 %
Age	875		
18–39	275	31.4 %	34.0 %
40–64	405	46.3 %	44.8 %
65 and older	195	22.3 %	21.2 %
Ethnicity	874		
Dutch	840	96.1 %	78.9 %
Other	34	3.9 %	21.1 %
Education level	841		
Low (none, primary school or prevocational education)	132	15.7 %	30.4 % ^b
Medium (secondary or vocational education)	484	57.6 %	40.3 % ^b
High (professional higher education or university)	225	26.8 %	28.3 % ^b

^a - Table 2 continues –

- Table 2 continued -

	Number	Study sample %	Dutch population (18 and older) 2013 %
Work in healthcare	846		not available
No, I have never worked in healthcare	590	69.7 %	
Yes, I am currently working in healthcare	122	14.4 %	
Yes, I worked in healthcare in the past	134	15.8 %	

^a Data about the Dutch population come from Statistics Netherlands

^b These percentages apply to the Dutch population aged 15–65 in 2012. The educational level of the remaining percentage is unknown

Respondents were asked what information sources the Inspectorate could best rely on to monitor healthcare quality (Fig. 1). The majority of respondents (93.2 %) agreed (totally or partially) that the Inspectorate could best rely on the complaints of patient associations. In addition, a large majority (87.1 %) agreed (totally or partially) that the Inspectorate should visit all care providers. In addition, the respondents' opinion was that the Inspectorate should rely on sources such as complaints of care providers (87.3 %) and members of the public (85.3 %). Fewer respondents (approximately half) agreed (totally or partially) that the Inspectorate should rely on information provided by care institutions themselves, whereas 23 % were of the opinion (totally or partially) that it should not.

Respondents were asked what measures the Inspectorate should take in cases of poor care (Fig. 2). If a healthcare provider delivers poor care, the majority indicated that the Inspectorate should double-check the care institution (96.4 %) and provide recommendations for improvements (93.9 %). In addition, about 70 % of respondents agreed (totally or partially) that the Inspectorate should publish poor care delivery on its website. With respect to other possible regulatory measures, allowances should be made for the fact that between 20 and 48 % of the respondents answered indifferently ('neither disagree nor agree'). Slightly more than half of the respondents indicated that the Inspectorate should issue a fine when poor care was provided. Furthermore, 53.3 % of the respondents agreed (totally or partially) that the Inspectorate should temporarily take over the management of a poorly performing care institution. Slightly more than a quarter of all respondents indicated that the healthcare institution should be closed if it provides poor care.

We analysed whether there were differences in the answers given by different age groups, educational levels and knowledge about the Inspectorate. Some significant differences were found. Less highly educated and older respondents tended to agree more often on some questions that the Inspectorate should respond more actively than suggested by respondents in the other categories.

Table 3 Mean scores on responsibility (1 = no responsibility, 5 = full responsibility) of various stakeholders for quality in the Dutch healthcare, education and food service industry (N = 819-838)^a

	Health care	Education	Food service
Dutch Healthcare Inspectorate Dutch Inspectorate of Education Netherlands Food and Consumer Product Safety Authority	4.42 ^a	4.52 ^a	4.36 ^a
Care providers Teachers Personnel who prepare food	4.29 ^a	4.46	4.43
Minister of Health, Welfare and Sports Minister of Education, Culture and Science Minister of Economic Affairs	4.17	4.23	3.74 ^a
Managers	4.11 ^a	4.38 ^a	4.41
Direct colleagues of care providers Direct colleagues of teachers Direct colleagues of personnel who prepare food	3.92 ^a	4.20 ^a	4.13 ^a
European Union	3.41 ^a	3.48 ^a	3.32 ^a
Patients Students and their parents Consumers	2.98	3.22	2.70

^a Significant score of responsibility compared to group of stakeholders with lower score. Intergroup comparisons were tested using the Wilcoxon signed rank test [47]. P-values of <0.05 were considered significant

For instance, respondents in the two older age groups and those with a low or medium level of education agreed more often that the Inspectorate should advise patients in cases of poor care delivery to go to another care institution and inform the media than respondents from the other groups did ($p = 0.000-0.001$). Furthermore, less highly educated respondents agreed more often that the Inspectorate should search the Internet for complaints about care providers than respondents from the other groups did ($p = 0.02$). In addition, less highly educated respondents agreed more often that the Healthcare Inspectorate should issue fines in cases of poor care delivery than more highly educated respondents ($p = 0.03$). Lastly, respondents who admitted a lack of knowledge about the Inspectorate's work, tended to answer indifferently more often on some questions.

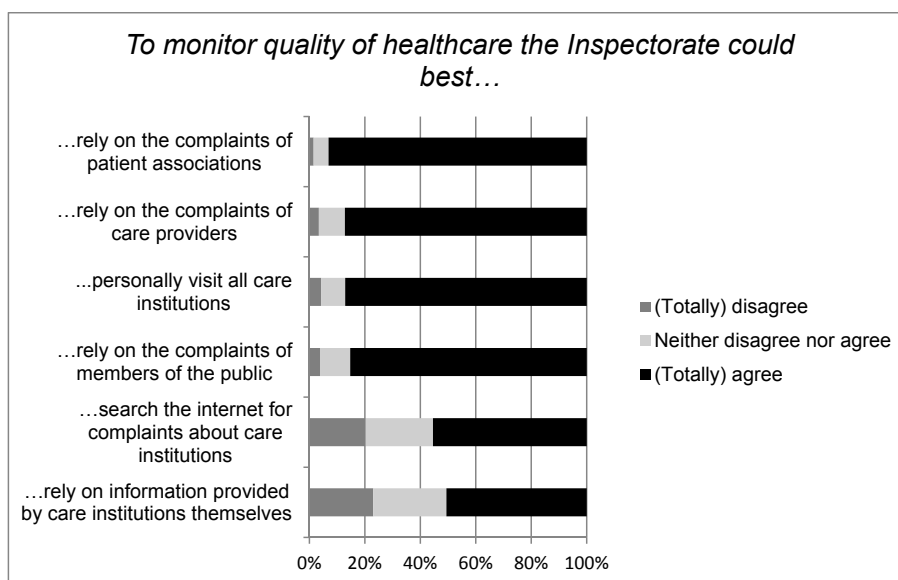


Figure 1 Evaluation of sources for monitoring healthcare quality by the Dutch Healthcare Inspectorate according to respondents of the Dutch Healthcare Consumer Panel ($N = 818-838$)

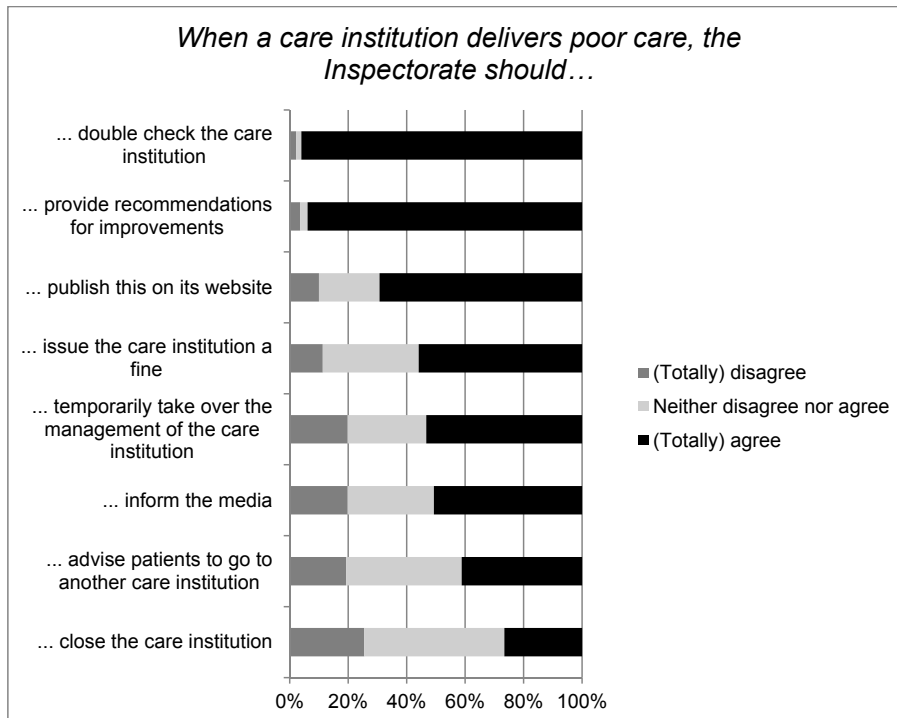


Figure 2 What the Healthcare Inspectorate should do when a care institution delivers poor care according to respondents of the Dutch Healthcare Consumer Panel ($N=818-832$)

Discussion

This study aimed to explore the opinions and values of the public regarding healthcare quality regulation policies, analysing the Dutch situation as a case study. Similarly to other countries such as the UK, the Netherlands had some high-profile incidents in which the regulator failed to respond to various emerging signals, including patients' complaints. These led to concerns about public confidence in healthcare and the regulator. Internationally, political visions on governance and regulation are changing from centralised to decentralised approaches and responsibilities are being shifted from the government to the field [4, 13–17]. In the Netherlands, this changing vision resulted in the introduction of the Quality Act in 1996, which made care providers primarily responsible for the quality of care. In this framework, regulation relies on internal monitoring and self-regulation, on the

basis of which the regulator monitors performance [17, 36]. This vision fits with the theory of responsive regulation, in which regulators entrust those being regulated to take their responsibilities [10]. This study shows that the majority of the public partly support this idea: the public assigned a high degree of responsibility to care providers. However, a fundamental discrepancy became apparent: the predominant rhetoric of decentralisation of responsibilities was not supported and the majority of the public seem to have little confidence in the internal monitoring of quality by care providers and the use of this information for regulation. Other studies also found that a large proportion of the public assign responsibility for promoting safety and preventing medical errors in healthcare to state agencies [31, 49]. Moreover, this study shows that there is a generalised idea among the public that the state regulator has a prominent role, as the same patterns were observed for the food service industry and the education sector. Apparently, according to the majority of the public, the internal monitoring of quality and safety of healthcare cannot simply be left to the goodwill of the care providers. Nevertheless, although some differing opinions were found among older and less well-educated respondents, the majority support the regulators' gradual approaches of imposing measures to care providers who fail to comply with quality standards, as proposed by the theory of responsive regulation [10]. Thus, the majority prefer a greater responsibility and an active role by the regulator with regard to gathering information but not a stricter approach with regard to imposing measures for the state regulator.

It has been stressed in several studies that more democratic approaches to regulation, such as 'tripartism', might overcome the conflicts of values that are important to the different stakeholders [3, 10, 18–21, 23]. On the one hand, the majority of the public attach importance to complaints of patient associations as a source of information for regulation. This is an interesting finding, as questions have been raised in several European countries about how patients' complaints should be valued and have a place in the regulatory process, and public participation in regulation is an important item on the policy agenda [2, 3, 5, 18, 24, 36, 37, 40]. The use of patients' complaints can be seen as a reduced form of tripartism whereby services become more responsive to and learn from their users. Actually, The Mid Staffordshire Public Inquiry showed that inferences about general patient safety can be gained from individual complaints. Moreover, in this case, individual complaints even indicated dramatic systemic failures [2]. A voice for the patients provides information about 'blind spots' that care providers are unaware

of; this is also called 'soft intelligence' [7]. In this respect, it should be investigated what value complaints could have for regulation of healthcare quality and what those who report complaints to regulators themselves expect from their complaint in the process of healthcare quality regulation. On the other hand, patients were also considered to bear least responsibility for quality of care by the public in this study. This might undermine the goals of the reform of marketisation in healthcare towards more 'active patient choice' and more responsibility for patients. Furthermore, the role of patient organisations and their expected role of participating in decision-making processes might be at stake [3, 12, 13, 22]. In addition, it might indicate that the majority of the public do not favour intensive or active methods of 'tripartism' in the regulatory process, but instead support more collective forms of participation. This suggestion requires further research, which should include the public's and patient's perspectives.

Strengths and weaknesses

One strength of this study is its large study sample. However, the response rate was moderate which may have caused non-response bias. This sample is comparable to the Dutch population in terms of age and gender, although not with respect to educational level. With respect to the different background variables, we analysed differences in answers. Some significant differences were found in the answers of older and less highly educated respondents. This means that different opinions of subgroups among the public can exist. This should be taken into account when involving the public in regulation policies.

It is striking that a considerable proportion of the respondents answered indifferently. This was also apparent in other studies on public perceptions of the Inspectorate [25, 26]. The regulator might be a 'low interest good', its visibility might be low, or respondents might have too little knowledge to answer the questions. However, less than 1 % answered indifferently on all items of Figs. 1 and 2, so this does not mean that the public have no opinions or expectations about healthcare regulation. Furthermore, people might have or might gradually develop more general or common-sense ideas about the Inspectorate and its responsibilities, especially when it attracts media attention. Lastly, it remains unsure whether the same questions about healthcare, food service industry and education sector have equal connotations to the respondents. Therefore, the outcomes with respect to the comparison of the three sectors should be interpreted cautiously.

Conclusion

Many countries face problems of public accountability, legitimacy and transparency of regulators. To tackle these issues, it is important that the values of regulatory policies are consistent with the values of the public. This study shows that there are discrepancies and similarities between public opinion and regulatory policies. A gradual, and often mild approach with regard to imposing measures to failing care providers, is favoured by the majority of the public in spite of the criticism that is voiced in the media regarding this approach. However, the majority of the public do not support decentralisation of responsibilities of the regulator. This applies not only to healthcare, but also to other industries. Furthermore, the majority agree that the patients' voice and especially their complaints should play a pivotal role in regulatory policies. Moreover, a form of collective participation by the general public or patients in the regulatory process can potentially overcome the conflict in values between the public and regulatory policies. It also provides information about 'blind spots'. It would be worthwhile to explore which specific forms of involvement of the public are most suitable while taking into account differing opinions of subgroups, as this would provide a valuable addition to the quality information delivered by healthcare providers. Our study contributes to the limited knowledge of public opinion on government regulation policies. This knowledge is needed in order to effectively assess different approaches to involve the public in regulation policies.

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Chapter 3

Patients' perspectives on the role of their complaints in the regulatory process

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Abstract

Background

Governments in several countries are facing problems concerning the accountability of regulators in health care. Questions have been raised about how patients' complaints should be valued in the regulatory process. However, it is not known what patients who made complaints expect to achieve in the process of health-care quality regulation.

Objective

To assess expectations and experiences of patients who complained to the regulator.

Design

Interviews were conducted with 11 people, and a questionnaire was submitted to 343 people who complained to the Dutch Health-care Inspectorate. The Inspectorate handled 92 of those complaints. This decision was based on the idea that the Inspectorate should only deal with complaints that relate to 'structural and severe' problems.

Results

The response rate was 54%. Self-reported severity of physical injury of complaints that were not handled was significantly lower than of complaints that were. Most respondents felt that their complaint indicated a structural and severe problem that the Inspectorate should act upon. The desire for penalties or personal satisfaction played a lesser role. Only a minority felt that their complaint had led to improvements in health-care quality.

Conclusions

Patients and the regulator share a common goal: improving health-care quality. However, patients' perceptions of the complaints' relevance differ from the regulator's perceptions. Regulators should favour more responsive approaches, going beyond assessing against exclusively clinical standards to identify the range of social problems associated with complaints about health care. Long-term learning commitment through public participation mechanisms can enhance accountability and improve the detection of problems in health care.

Introduction

In a number of countries, high-profile incidents in health care have led to critical re-examinations of the roles of regulators. Governments are facing problems concerning organizational failures, public confidence in regulators and accountability of regulators [1-7]. One widely discussed incident is the Mid Staffordshire Trust hospital scandal in the UK. In this case, several regulatory agencies including the government failed to respond to various emerging signals including patient complaints. Major lapses in health-care quality remained unnoticed, and mortality rates increased between 2005 and 2009 due to appalling care [3, 4]. It was concluded that 'complaints were not given a high enough priority in identifying issues and learning lessons' [4]. The approach taken by the regulator gave the appearance of looking for reasons for not taking action rather than acting in the public interest. Public confidence in the regulator and the health-care system could therefore not be maintained [4, 8]. Other countries such as New Zealand, the USA and the Netherlands are facing similar problems with public confidence, and it has become more important that there should be reform in safety cultures that deal with public demands for greater accountability from health services and regulators [5,9,10]. Furthermore, political attention for the use of information from patients, including complaints, and improving public participation in regulatory processes has increased [6, 8, 11, 12]. This development can be seen in the way that increased attention is now being paid to reinforcing patient's positions in health care [13].

Complaints by patients in general and utilization of such complaints for regulating health-care quality are much debated topics in many countries. However, we were concerned to note that no research has been performed on what patients with complaints expect from a regulator.

This article therefore aimed to seek an answer to the following questions, using the Dutch situation as a case study:¹

- What is the subject and nature of complaints submitted by patients to the Dutch Health-care Inspectorate?

¹ This study was carried out independently of the Dutch Health-care Inspectorate. Cooperation was provided by the Inspectorate through selecting and contacting complainants for this study, to protect their privacy

- How do patients with complaints rate the severity of the physical harm that has been carried out? And are differences observed between patients whose complaints were and were not handled by the Inspectorate?
- What outcome do patients who submitted complaints to the Inspectorate expect from the complaint handling, and are there differences between the aforementioned groups (handled and not handled)?
- Are those expectations met?

The following sections address the theoretical concepts underlying regulation policies, current policies in the Netherlands regarding complaints about regulatory processes, followed by the Methods, Results, Discussion and Conclusions.

Theoretical framework: regulation, public participation and complaints

Internationally, the ‘responsive regulation’ theory of Ayres and Braithwaite (1992) is the basis for regulation policies in various industries such as finance, environmental businesses and health care. This theory assumes that the relationship between the regulator and regulated parties is based on co-operation and trust. Regulation based on distrust would only lead to more penalties being imposed and therefore requires more capacity on the part of the regulator and ultimately leads to higher societal costs. Regulatory compliance is encouraged firstly by using more lightweight measures such as persuasion and secondly by applying more weighty measures in the case of riskier behaviour by the regulated parties. This principle is also known as ‘the stick or the carrot’ [14]. Another important element of the theory is ‘tripartism’, whereby a third group such as patients or consumers is involved in the regulatory process.

This is proposed as an approach for empowering public interest groups by giving them a voice and letting them participate. This ought also to enhance the legitimacy and accountability of a regulator. Furthermore, it could prevent regulatory capture and value conflicts between different stakeholders [1, 14-17]. The use of patients’ complaints for regulatory purposes can be considered as a form of tripartism in which the services learn from their users. Research has already shown that complaints can add value to regular regulatory monitoring systems [18-20].

When comparing different complaints procedures with different goals such as

individual complainant satisfaction or disciplinary complaint procedures, complainants seem rather unanimous in what they expect of the procedures. For most people, it is important that their sense of justice is restored and that the problem is prevented from recurring [21-24]. However, the majority of complainants believe that no changes are made in response to their complaint [21, 22, 25].

Complaints in the Dutch regulatory system

Internationally, changing political views on approaches to governance and regulation have resulted in shifts from centralized to decentralized systems, with governmental authorities retreating and leaving responsibility to those in the field [2, 13, 26]. In the Netherlands, those changing views resulted in the adoption of the Quality Act in 1996, placing responsibility for healthcare quality primarily with care providers. This responsibility also includes handling individual complaints from patients about health care. The Dutch Health-care Inspectorate is an independent part of the Ministry of Health, Welfare and Sports and is mandated to supervise and regulate health-care quality. The Inspectorate supervises compliance with obligations imposed by legislation, assuming that care providers have an intrinsic motivation to act rationally and socially responsibly, according to the theory of responsive regulation [14]. It is possible for patients to register complaints about health care with the Inspectorate. The statutory tasks of the Inspectorate do not let it give individual judgments about complaints. Instead, it uses complaints for general risk analyses. Complaints are only eligible for handling by the Inspectorate and further investigation when complaints meet the following specific criteria: severe deviation from the applicable professional standards by professional or other employees within the institution, severe failure or the absence of an internal quality system at an institution, severe harm to health or a high probability of recurrence of the problem [27]. If the complaint meets one of the criteria, the Inspectorate firstly entrusts the care provider in question to investigate the problem, which is in line with the theory of responsive regulation. If necessary, the Inspectorate starts its own investigation. If the complaint does not meet any of the criteria, the Inspectorate must ensure that the complainant receives information about other options for obtaining a judgment [27, 28].

The Inspectorate receives approximately 1400 complaints by patients each year of which the majority are not handled by the Inspectorate, given its statutory task [28]. However, as in the UK, it was argued that the Inspectorate does not take

patients and their complaints seriously and does not value patients' complaints as signalling deeper problems [2, 4, 29-31]. It was stated in political debates and by the Dutch ombudsman that the patients and their complaints deserve more attention and should be involved in regulation policies to reflect patients' needs [29-31]. Previous research demonstrated that the Dutch general public also agreed that patients' complaints should be an important source of information for regulation of health-care quality [32].

Methods

In this study, existing questionnaires developed in previous studies among complainants at complaint boards and disciplinary boards were used to develop a new questionnaire. Interviews were conducted with complainants at the Inspectorate to examine whether those questionnaires were applicable to this target group.

Development of the questionnaire

The questionnaire that was developed was mainly based upon questionnaires used in previous research about expectations and experiences of complainants in health care (to complaint boards and disciplinary boards) [33-35]. The design of those questionnaires was driven by the theory of procedural, distributive and interactional justice [36]. Information from the interviews was used to adjust the questionnaire specifically to the characteristics of the regulator. Interviews were conducted with people who had made a complaint to the Inspectorate to identify whether the questionnaires would also apply to this setting. The Inspectorate contacted a sample of 25 people with complaints about a wide variety of health-care sectors, who could then voluntarily sign up for the interviews with the first author. Eleven people signed up. During five interviews, a second interviewee participated. In total, nine males and seven females were interviewed. Subjects of the complaints were hospital care, ambulance services, mental health care, pharmacy, care for disabled and nursing homes. Respondents could indicate their preference for the interview location. Most chose to be interviewed at their home. Three interviews were conducted by telephone. The interview consisted of open questions using a topic list. Questions were focused on the complaint itself, the reasons for submitting the complaint to the Inspectorate, the expectations and the

experiences when reporting to the Inspectorate. Interviews lasting 30–100 min were recorded with permission of the interviewee. After the interview, the recordings were listened again, and a summarizing report was made and sent to the interviewee for approval. New themes derived from the interview reports were added to the questionnaire. New themes included for instance expectations regarding measures that lie within the competence of the Inspectorate as opposed to complaint boards, health-care sectors other than hospitals and subjects that can be complained about (e.g. complaints procedure of complaint boards at hospitals). Face validity and content validity were assessed by submitting the questionnaire to two of the people who had been interviewed previously and three employees working at the complaints desk of the Dutch Health-care Inspectorate, because of their experience with communicating with patients with complaints.

The questionnaire contained three domains:

(i) characteristics of the person and complaint (subject and severity of physical injury); (ii) peoples' motives and expectations when reporting to the Inspectorate; and (iii) what is achieved by reporting. Severity of physical injury caused by the situation the complaint was about was measured on a 5-point scale (1 = no physical injury, 2 = slight physical injury, 3 = severe physical injury, 4 = permanent physical injury, 5 = death). The questions about expectations were in the form of statements for which respondents could indicate how important the specific statement was to them. Subsequently, respondents were asked to what degree they felt that these statements actually applied (experiences). People's expectations making the complaint (from 'not important' to 'most important') and experiences with the reporting (from 'no' to 'yes') were measured on a 4-point scale. According to the theory of responsive regulation, milder to more severe measures that could be taken by the Inspectorate were included to assess whether respondents agree with the stick or carrot approach. Examples of the questions about the expectations are 'I made my complaint to the Inspectorate because I wanted to improve quality of care' or 'I made my complaint to the Inspectorate because I wanted the care provider in question to be punished'. Subsequently, examples of the questions about experiences are 'Making my complaint to the Inspectorate led to the quality of care being improved' or 'Making my complaint to the Inspectorate led to the care provider in question being punished'.

Selection of the study population

The questionnaire was sent to all 343 people who submitted a complaint to the Inspectorate between August 2012 and November 2012.

Several inclusion criteria were formulated as follows:

- The complaint has to be submitted by a member of the public/patient, not a care provider.
- The complaint must be about health care (so general questions or complaints about the Inspectorate itself were excluded).
- Handling of the complaint must be closed from the perspective of the Inspectorate, and the complainant had to have been informed about the closure by letter, so as to minimize the risk of respondents assuming that their response would have an impact on how their complaint would be dealt with.

An employee of the Inspectorate ensured the complaints met the inclusion criteria.

As described earlier, the Inspectorate is expected to only handle complaints by members of the public when they are severe or structural. Therefore, based on the information from the Inspectorate, two groups could be distinguished within the sample in advance: members of the public whose complaints were handled by the Inspectorate ($n = 92$, 27%) and those whose complaints were not handled by the Inspectorate ($n = 251$, 73%), because of the considerations mentioned earlier.

Two reminders were sent. After this, the response rate was modest (47%). A substantially abridged questionnaire was sent by post to non-responders; 29 respondents dropped out because their addresses were incorrect, the person had moved, or the person was deceased. The response is shown in a flow chart (Fig. 1).

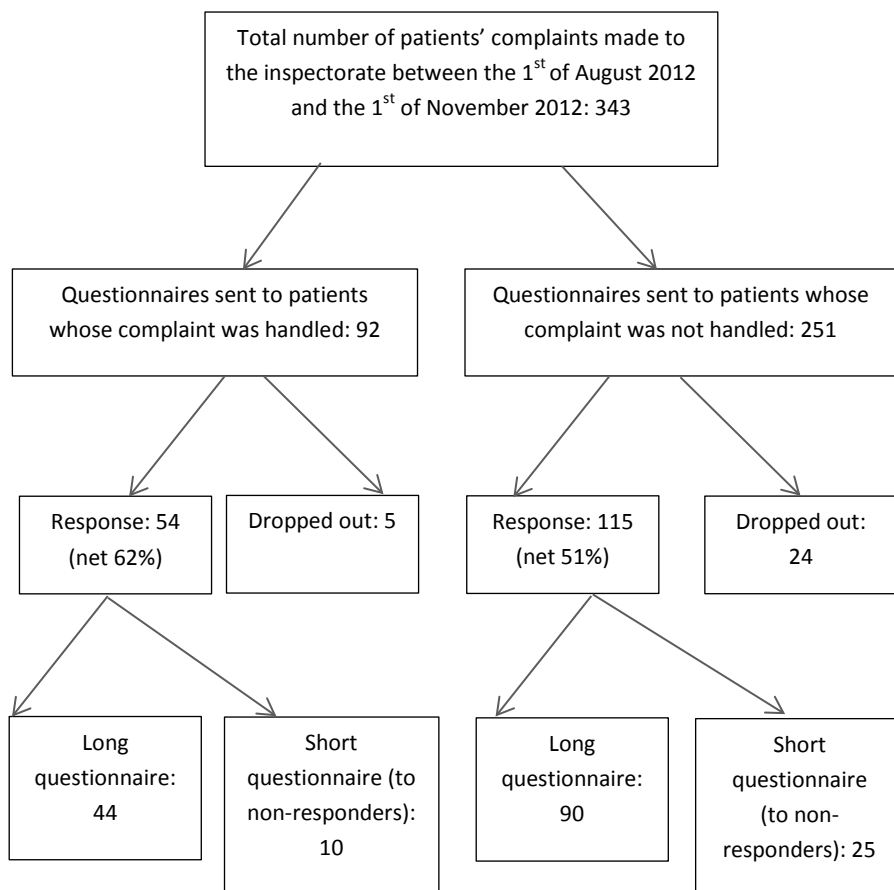


Figure 1 Flow chart of responses to the questionnaire

Ethics statement

The protocol for this study was submitted to an external Medical Research Ethics Committee for formal ethical approval. This committee concluded that formal ethical approval for this study was not required according to Dutch law, as the study does not involve a medical intervention. Privacy was guaranteed because research data and addresses and names were kept separate. Questionnaires were sent by post by the Inspectorate itself. The questionnaires contained unique coded usernames and passwords, giving respondents the opportunity to complete the questionnaire online. It was stressed that people were entirely free to decide whether or not to complete the questionnaire and they could return the

questionnaire to the researchers anonymously. It was explicitly stated that their individual answers to the questionnaire would not be revealed to the Inspectorate. The researcher kept a list of respondent codes that were also printed on each questionnaire, and the Inspectorate kept a list with the same codes and the associated names and addresses. This allowed response rates to be monitored and reminders could be sent by the Inspectorate to non-responders. The list of codes was destroyed after 6 months.

Statistical analyses

Statistical analyses were conducted using the software program STATA version 13 (Stata-Corp., College Station, Texas, USA). Background characteristics of the study population were compared to the characteristics of the Dutch population [37]. Population characteristics and nature of the complaints are presented descriptively. Differences in severity of physical injury between the two groups (those whose complaints were and were not handled) were calculated using t-tests to compare means.

Exploratory factor analysis (principal component analysis) with varimax rotation was carried out to identify latent relationships between the expectation variables. Communalities, eigenvalues, scree plots, explained variance and factor loadings were examined to determine the factor structure. The Kaiser–Meyer–Olkin (KMO) test and Bartlett’s test of sphericity were conducted with the purpose of confirming the adequacy of the sample for this analysis. Items with a factor loading ≥ 0.40 were included in scales. Reliability of the scales was assessed using Crohnbach’s alpha. New variables were created for the scales to calculate mean scores of importance. Missing values, which were mostly related to respondents who completed the short questionnaire, were left out. Differences between the scores of the groups whose complaints were and were not handled were analysed using t-tests. Differences were considered significant if $p < 0.05$. Percentages of which expectations are actually met according to the respondents were calculated by adding scores 3 and 4 of each variable.

Results

The response rate to the questionnaire was 54%. Basic study population characteristics are shown in Table 1. Background characteristics are not available for all respondents. Slightly more than half of the respondents were female. Relatively more respondents were aged 40–64 than in the Dutch population at large. The study population consisted of relatively more well-educated people and relatively few people with ethnic backgrounds other than Dutch.

Table 1 Background characteristics of the respondents (n = 127–131) compared to the Dutch population

	N (Respon- dents)	%	Dutch population (aged 18 and older) 2013% [37]
Gender	128		
Female	70	55	51
Male	58	45	49
Age	129		
18-39	16	12	34
40-64	79	61	45
65 and older	34	26	21
Educational level	127		
Low (none primary school or pre-vocational education)	30	24	30*
Middle (secondary or vocational education)	37	29	40*
High (professional higher education of university)	60	47	28*
Unknown		-	2
Ethnicity	131		
Dutch	127	97	79
Other	4	3	21

*These percentages apply to the Dutch population aged 15–65 in 2012.

Nature and subject of complaints

Table 2 shows the type of care that complaints made to the Inspectorate were about. Three types of care were complained about most often: 22% about nursing homes and residential care, 19% about hospital care and 19% about mental health care. Fewer than 15% of the complaints were about care provided by general practitioners, care for disabled patients, care in private clinics, care involving medical technology, home care, dental care, community care, drug therapy or physical therapy.

Table 2 Type of care that complaints made to the Inspectorate were about

Type of care complaint is about	N = 133 (%)
Nursing homes/residential care	22
Hospital care	19
Mental care	19
Drug therapy	14
General practitioner	11
Care for disabled	8
Private clinic	7
Medical technology	5
Home care	4
Community care	2
Physical therapy	1
Other	18

Four of ten (39%) respondents submitted complaints concerning interpersonal conduct, and 37% of the complaints involved medical treatment (Table 3). However, almost all complaints about interpersonal conduct were submitted in combination with another subject. One of five respondents complained about a lack of information, quality of nursing care or collaboration between care providers. Other complaints concerned the complaints procedure of the care provider, organizational aspects or sexual harassment. A substantial proportion of respondents used the 'other' category and the accompanying option for an open answer. Box 1 shows some examples of complaints described in the open answer option.

Table 3 Subject of complaints made to the Inspectorate

Subject of complaint	N = 133 (%)
Interpersonal conduct	39
Medical treatment	37
Information or education	23
Nursing care	22
Collaboration between care providers	22
Complaints procedure	14
Organizational aspects	10
Sexual harassment	9
Other	38

In more than half of the cases (52%), another person was involved in the complaint than the complainant themselves, for instance spouse, child, parent or grandparent (not in table).

The severity of the physical injury caused differed significantly between the two groups: respondents whose complaints were handled reported an average of 2.9 on a 5-point scale, while respondents whose complaints were not handled reported an average of 2.1 (not in table).

Box 1 Examples of complaints by respondents (handled and not handled),
derived from open answer option

Not handled:

Poor hygiene on the nursing ward. Cleaners who do not understand the word 'cleaning'. Nurses who do not wash their hands.

Tubes with blood were left unattended in the hallway.

Medication that my cardiologist says I have to use (because of a metal cardiac valve) was not delivered. As a result, I had to go to the hospital urgently with the ambulance because of heart problems.

Errors were regularly made with medication, wrong dose of insulin, wrong antibiotics, for example after switching the type of antibiotics, the old one was given. It seems as if the referrals do not happen.

Cardiologist kept practicing although he was banned. Patients were not informed.

The complaint concerns unsuccessful operations, lack of supervision, off-label medication with serious side-effects.

Handled:

Wrong insulin injection, several times. Wet pyjamas, not changed 3 times a day [...] Eating times forgotten, food and drinks left for days [...]

That pregnyl could not be obtained through the regular channels, but through web shops for bodybuilders.

The call made by a child to 911 was not accepted three times. After twelve hours, I alerted 911 again. Then, they reacted.

Title misuse, fraud.

Aggressive cleaning products are within reach for the clients at bath times.

Expectations from submitting complaints to the Inspectorate

Table 4 shows the factor analysis conducted for the expectation variables. The KMO test of sampling adequacy and Bartlett's test of sphericity were used for confirming the adequacy of the sample for the analysis. The obtained values were 0.832 and 0.000, respectively. The factor analysis produced three meaningful scales, clearly distinguishing between different perspectives. The first scale refers to the consequences for the care provider (6 items, $\alpha = 0.85$, explained variance 65%). The second scale refers to the public domain: the quality of health care in general (4 items, $\alpha = 0.77$, explained variance 25%). The third scale refers to the individual domain: the benefits of complaining for the person that made the complaint (4 items, $\alpha = 0.79$, explained variance 9%). Two items were excluded from the scales because they seem to be more general and less tangible consequences of making a complaint to the Inspectorate. One of them, 'to prevent the complaint from remaining indoors' (avg score of importance: 2.9), did not fit in

any of the scales. The other one, 'to ensure the complaint to be taken up at a higher level' (avg score of importance: 3.3), cross-loaded on two of the three scales. Table 4 also shows average scores of importance according to respondents of the specific expectations and the three scales developed. Furthermore, the expectations are shown separately for the two groups (complaint handled vs. not handled). Expectations regarding the dimension 'benefits for quality of care in general' were considered most important by respondents, followed by expectations regarding 'personal benefits'. Expectations regarding 'specific consequences for the care provider' were considered to be least important. A significant difference was only found between the two groups for one item (financial compensation for the damage to be offered).

Experiences when submitting complaints to the Inspectorate

Figure 2 shows which aspects respondents felt had been achieved by making their complaint to the Inspectorate. A distinction was made between respondents whose complaints were handled by the Inspectorate and those whose complaints were not. Large differences were seen between the two groups. Respondents whose complaints were handled indicated that aspects were achieved more often than respondents whose complaints were not handled. About 50% of the respondents whose complaints were handled indicated that aspects regarding the dimension 'benefits for quality of care in general' were achieved. Fewer than 40% indicated that aspects regarding the other two scales were achieved (except 'doing your duty' – an aspect that respondents have more control of – which was achieved according to 68–88% of the respondents).

Table 4 Factor analysis of what respondents expected from making their complaint to the Inspectorate and average scores of importance for the scales that were developed (1 = not important to 4 = most important)

Avg. score for handled complaints (N = 37-42)	Avg. score for complaints that were not handled (N = 77-85)	I made my complaint to the Inspectorate because I wanted...	Factor 1	Factor 2	Factor 3
3.6	3.5	Benefits for quality of health care in general			
3.6	3.6	The care institution to learn from my complaint	-0.0302	0.4967	0.2651
3.7	3.5	To prevent it happening to others	-0.0374	0.6821	0.0065
3.6	3.6	To improve the quality of health care	0.0947	0.7667	0.0407
3.5	3.5	To improve the safety of health care	0.0339	0.6726	0.1504
2.7	2.7	Personal benefits			
2.5	2.8	To restore my sense of justice	0.4468	0.1202	0.5439
2.8	2.9	A solution to my problem	0.3586	0.0511	0.7307
3.2	2.8	To prevent it from happening to me again	0.1232	0.3600	0.5101
2.2	2.5	The damage to be repaired	0.5201	0.0593	0.5947

- table 4 continues -

- table 4 continued -

Avg. score for handled complaints (N = 37-42)	Avg. score for complaints that were not handled (N = 77-85)	I made my complaint to the Inspectorate because I wanted...	Factor 1	Factor 2	Factor 3
2.1	2.4	Specific consequences for care provider			
1.5*	2*	Financial compensation for the damage to be offered	0.6232	-0.0388	0.3793
2.1	2.4	The care provider in question to be banned from working	0.8709	-0.0023	0.1806
2.8	3	The Inspectorate to have a hard-hitting conversation with the care provider in question	0.4700	0.2132	0.4470
2.1	2.4	The care provider in question to be punished	0.8628	0.0012	0.2191
1.6	1.7	The department of the care institution to be closed	0.6601	0.1489	0.1092
2.8	2.8	To do my duty by making a complaint	0.5118	0.1768	0.1533
		Cronbach's alpha	0.85	0.77	0.79

* Significant difference between groups, P-value < 0.05.

** Bold values represent average scores of importance for the developed scales and the factor loadings of the items belonging to the specific scales.

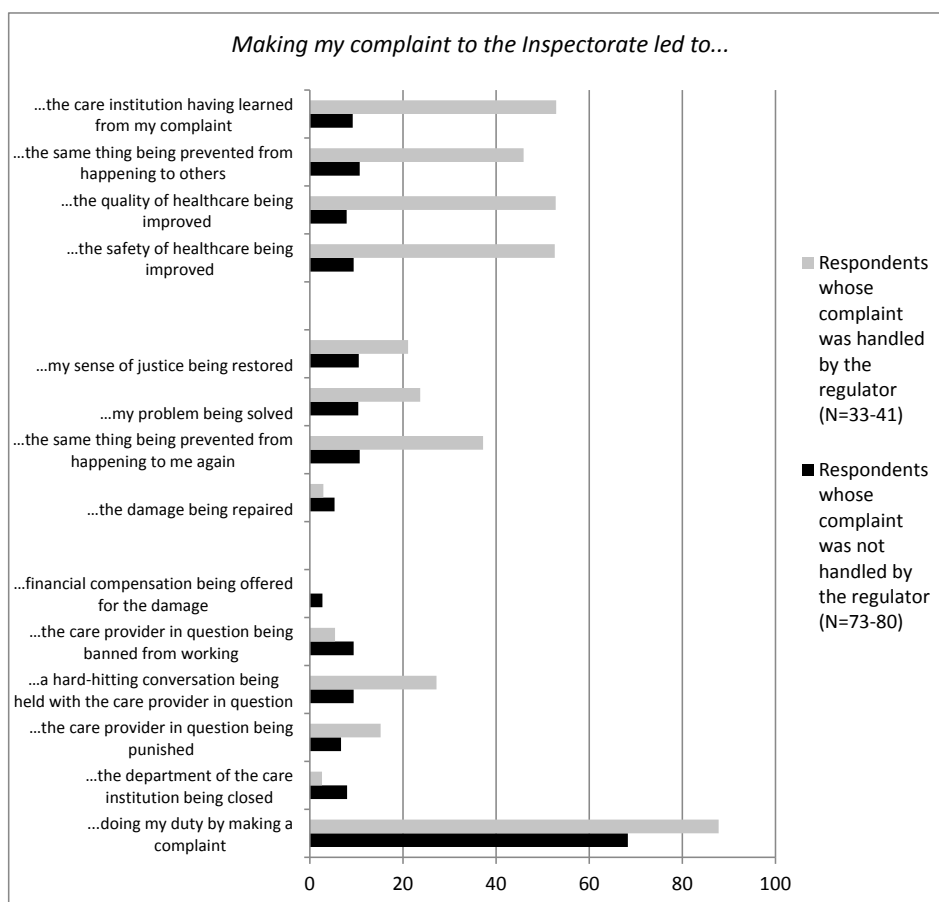


Figure 2 Percentages of what is actually achieved according to respondents (items were measured on a four-point scale (no to yes). Percentages presented in this figure are based on scores 3 and 4 of each variable

Discussion

Several countries, including at least the UK and the Netherlands, are struggling with accountability issues when dealing with patients and their complaints [1, 3, 4, 28-30]. This article contributes by giving insights into what role patients themselves expect their complaints to have in the regulatory process. Complaints of patients in this study were mostly about nursing homes, hospital care and mental health care. Most prevalent subjects of complaints were the medical treatment and interpersonal conduct, although the latter most often in combination with another subject. The self-reported severity of the physical injury was significantly higher among patients whose complaints were handled by the Inspectorate. By reporting their complaint to the Inspectorate, patients aim to improve quality of health care. However, a minority felt this has been accomplished.

Expectations

Three main dimensions became apparent in what patients with complaints expect from a regulator: expectations regarding consequences for the care provider in question, personal benefits and benefits for quality of health care. Mean importance of the expectation scales was measured on a 4-point scale (1 = not important, 4 = most important). This means that a score of 1.5 would be the neutral point on the scale and every score above 1.5 can be considered important. Most items were therefore considered important by respondents to some extent, but gradations can be distinguished. Expectations regarding improving quality of care were considered most important by respondents. Furthermore, personal benefits and consequences for the care provider were seen as less important. Particularly rigorous consequences are less favoured by respondents, which is in line with the stick or carrot principle of the theory of responsive regulation [14]. The expectations largely correspond to what people expect of other complaints procedures, although slight variations can be observed. Complainants to complaint boards indicated that personal benefits were more important compared to complainants to the regulator. The same applied to complainants to disciplinary boards: consequences for the care provider were considered more important compared to what is important for complainants to the regulator [21, 24].

The majority of the complaints by the study population (73%) are not handled by the Inspectorate. The self-reported severity of physical injury in complaints that are not handled is lower than for complaints that are handled by the Inspectorate.

The Inspectorate and complainants' estimates of the severity of physical injuries seem to correspond. However, no differences were found between the expectations of the two groups. This means that despite the severity of physical injury involved in the complaint, complainants' perceptions of the relevance of complaints differ from what the regulators perceive. People feel that their complaint indicates deeper structural problems that can recur. Sharpe and Faden [9] have already argued that current patient safety evaluations tend 'to reflect a narrowly clinical interpretation of harm that excludes non-clinical or non-disease-specific outcomes that the patient may consider harmful'. As seen in other studies [38-41], these results stress the importance of recognizing that lay people have their own interpretations of patient safety that may conflict with current evaluation methods.

Experiences

As in other studies about complainants' expectations [22, 23], this study found a gap between what complainants expect and what is achieved by submitting their complaint. For many respondents, it was unclear whether submitting their complaint had led to improvements, although this was their main driving force behind making a complaint. Although it is not surprising that what is achieved differs widely between the two groups, it should be noted that the group whose complaints were handled also felt that little was achieved by reporting to the Inspectorate. Previous research among complainants to hospital complaint boards revealed that most patients were not kept informed about the measures taken in response to their complaints [22]. These results stress the need for complaint handlers to invest more in feeding back information to complainants about what actions were taken as a result of their complaint.

The respondents in this study seem to feel a sense of duty to make their complaints. They want to contribute to the improvement of quality of care and prevent recurrence. This indicates that they feel that they are a stakeholder in the process of improving health-care quality and want to be involved. Other research among patients who experienced medical errors shows that those patients often have strong opinions and views about patient safety, accountability and system reforms [7, 25].

Negative experiences of patients internationally created the demand for reforming safety cultures at care institutions. However, research suggests that those experiences have been neglected in patient safety reforms, due to power

imbalances that exist between patients and care providers [7, 11].

Using complaints for regulation

In this study, the complaints also concerned the ‘softer’ or non-clinical aspects of caring, such as interpersonal conduct. Patients provide ‘soft intelligence’ – information about blind spots that care providers are unaware of [5] – and the added value that this has for traditional monitoring systems such as incident reporting systems and regulatory visits has been proved [20]. However, as the majority of the complaints in this study were not handled because the regulator is not there to deal with individual complaints, consideration should be given to whether complaints could be used more effectively for regulating health-care quality systematically. Research has demonstrated that most medical errors never result in a complaint, so cases where individual complaints are submitted provide a valuable window on patient safety in general [18, 19]. Actually, the Mid Staffordshire NHS Foundation Trust Public Inquiry showed that individual complaints provided important signals for dramatic system failures [4], and it was recommended that complaints should be included in the regulatory process [8]. In addition, it has already been stressed that setting up continuous and non-sporadic public participation mechanisms and long-term learning commitment are essential for good regulatory design and would ensure accountability [1, 14-17].

Strengths and weaknesses

The response rate in this study was modest, even after sending two reminders and a shortened questionnaire. There is therefore a risk of response bias. Non-response analysis was not possible because no characteristics of the non-respondents are available, in part due to meticulous privacy regulations. Some respondents contacted us with questions about the study. Others indicated that completing the questionnaire made them uncomfortable because it revived the situation that the complaint was about. This could be an important reason for the non-response. Another reason could be that filing the complaint itself had already cost much effort, making people reluctant to participate.

The study population was not large; however, power was sufficient for the statistical analyses. Furthermore, the study population is older and more highly educated than the general Dutch population. This might be explained by the fact that this specific group feel more empowered to make their complaint to the regulator. Another observation is that respondents often chose the ‘other’ answer

category and used the option of adding details about their complaint in open answer categories. This emphasizes the complexity and diversity of the complaints, which are not easy to subdivide into standard categories.

Conclusions

Complaints by patients and the use of complaints for regulation of health-care quality are widely discussed topics in many countries. We were, however, concerned to note that no research has been carried out on what patients with complaints expect from a regulator. Patients with complaints and the Dutch Health-care Inspectorate share a common goal: improving the quality of health care. Patients feel that they are a stakeholder in the process of regulating health-care quality. The Inspectorate is not there to handle individual complaints. Patients who file a complaint with the Inspectorate seem to be aware of this, as evidenced by the low need expectations regarding personal satisfaction among patients who made complaints. The self-reported severity of physical injuries caused was lower among complaints that were not handled, which is in line with the severity-based assessment of the Inspectorate. However, patients' perceptions of the relevance of their complaint differ from what the regulators perceive. Furthermore, only a minority felt that their complaint led to improvements, which was the primary reason for patients making complaints. To improve this, the value of complaints for regulation could be disclosed at an aggregate level. Regulators should move away from traditional standardized procedures and favour more responsive and strategic approaches for responding to complainants. This approach needs to go beyond assessing against exclusively clinical standards to identify the range of social problems associated with complaints about health care.

Long-term learning commitment through public participation mechanisms can have the effect of enhancing accountability and improving the detection of problems in health care. It is therefore worthwhile to explore which specific forms (including the use of complaints) are most desirable to the public, most suitable and provide a valuable addition to the regulatory process. A thorough examination should be made of what information complaints by patients contain and what they can contribute to existing monitoring systems. How to collect and utilize complaints data to improve the quality of health care at the system level is a challenge that it would be worth exploring.

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Chapter 4

Including patients' complaints in healthcare quality regulation systems: testing the reliability of a taxonomy

Submitted as:

Bouwman, R., Bomhoff, M., Robben, P. and Friele, R. Including patients' complaints in healthcare quality regulation systems: testing the reliability of a taxonomy.

Abstract

Background

After some high profile incidents in several countries, the attention for the reporting and use of patients' complaints by healthcare quality regulators is increasing. However, there are no standardised techniques for analysing complaints, covering a wide array of healthcare sectors. Moreover, research on complaint analyses (including reliability analyses) is scarce. We aimed to provide a taxonomy for healthcare quality regulators, in order to encode complaints, and empirically test that taxonomy to determine its reliability.

Methods

An existing taxonomy from Reader *et al.* was developed into a taxonomy that is more broadly applicable to the regulatory setting of a wide array of healthcare sectors (18 different sectors). A sample of 364 complaints received by the Dutch Healthcare Inspectorate was selected to further develop and test the taxonomy by two raters. Percentage agreement and Cohen's kappa was calculated to determine inter-rater reliability of the taxonomy.

Results

The final taxonomy consists of 3 domains, 6 main categories and 29 subcategories, and a separate domain for complex complaints that include more than three themes. Reliability of four main categories was substantial (quality & safety, human rights, organisational & institutional problems, complex complaints), and reliability of two main categories was moderate (communication, timing & accessibility). The mean kappa of the taxonomy on main category level was 0.64 (range 0.50-0.75).

Conclusions

The taxonomy turns out to be a substantially reliable instrument for encoding patients' complaints about a broad diversity of healthcare sectors. An explanation for moderate kappa values could be that assessment of complaints is subjective and many complaints are multifactorial and unstructured. In contrast with other patient safety studies focused on adverse events, this taxonomy is able to capture the 'softer' or non-clinical aspects of caring that are important to patients. Standardised coding of patients' complaints permits consistent and reliable documentation, which could help make regulators more accountable. The

taxonomy could be used by regulators for analysing patients' complaints, transforming this from a regular compliance activity into opportunities for quality improvement, better patient satisfaction and enhancing public accountability.

Introduction

In several countries, some high profile incidents signalled by patients have been highlighted in the media. Criticisms expressed were often directed at regulators' failure to respond to patients' complaints. Attention for the use of patients' complaints for regulating healthcare quality has therefore increased [1-5]. Complaints often mention aspects that are not detected by traditional monitoring systems [6-10]. In the Mid Staffordshire NHS Foundation Trust scandal case, for example, individual complaints indicated dramatic system failures [11]. In the evaluation of this case, it was recommended that a greater role should be given to complaints within the regulatory process [2]. The Care Quality Commission has expressed commitment to pay more attention to patient complaints within its regulation policies [12]. In the Netherlands as well, the regulator was criticised for not responding adequately to complaints. The Dutch Healthcare Inspectorate receives approximately 1400 complaints from the general public every year of which the majority are only received and not handled by the inspectorate (for more information, see box 1) [13]. However, politicians and the Dutch ombudsman stated that patients and their complaints should be involved in regulation policies in order to reflect their needs and problems [14, 15]. Similar developments can be seen in other countries such as Australia and the UK, where awareness for public participation and including complaints in regulation policies is increasing [1, 2, 12, 16-19].

Using complaint datasets

Aggregated analysis of complaint datasets by regulators could serve several goals. It would add to the range of regulatory tools used for monitoring and improving healthcare systems [20]. Complaints concern not only adverse events and incidents, but also include a variety of problems that patients think should be prevented from recurring and can be learned from [21]. Furthermore, reporting about complaint data to society could contribute to the public accountability of regulators, because it might give patients reason to feel more confident about how

their complaints influenced the healthcare system [20, 21]. However, there are no standardised techniques for analysing complaints by patients in terms of regulating patient safety and covering a wide array of types of healthcare [22, 23]. Besides, research into complaint analyses, including reliability analysis which is standard in research into adverse events and their contributory factors of, is as yet scarce [24-26]. We therefore investigated the possibility of providing such a reliable standardisation technique in terms of a taxonomy for the use by healthcare quality regulators in practice, in order to encode patients' complaints about various healthcare sectors (see box 1) and use those for regulatory purposes on aggregate level, complementary to the handling of individual complaints. Furthermore, we empirically tested the taxonomy in order to determine its reliability, using the Netherlands as a case study.

Testing a taxonomy

Recently, Reader *et al.* (2014) developed a taxonomy for standardising the analysis of patient complaints, with the aim of supporting research and practice in analysing information reported in patient complaint letters. In his article, 59 studies on complaints from primarily hospital patients were analysed. These were conducted in various countries [27, 28], including the Netherlands, covering about 88,000 complaints in total. The taxonomy differentiates between clinical, management and relationship domains. This classification corresponds to sociological theories about conflicts between the macrosystem and life world within medical systems [29], human factors theory on how humans interact with complex systems [30], and dialogical and intersubjectivity theories on the relation between people's perspectives and how those are shaped [31]. The three domains are subdivided into seven main categories (quality, safety, institutional issues, timing & access, communication, humaneness/caring, patients' rights) and those are subdivided into 26 subcategories. Reliability and usability of the taxonomy was not assessed, but the authors recommended those assessments [23]. Therefore, in this study, we took Reader's taxonomy, and further developed it and assessed its reliability. To make it reliable and applicable for the use by an Inspectorate some adaptations were needed. Firstly, it is based mostly on complaints in hospitals, whereas the Dutch HealthCare Inspectorate supervises a wide array of different healthcare sectors (see box 1). Secondly, the taxonomy was not developed with regulation policies in mind, this required the addition of a few sub-categories, referring to the upholding of specific legislation.

Box 1 Complaint handling by the Dutch Healthcare Inspectorate

In the Netherlands, the Dutch Healthcare Inspectorate is the appointed body for supervision and regulation of the quality of healthcare. It is an independent part of the Ministry of Health, Welfare and Sports. Both care providers and the public can report incidents or lodge complaints with the Inspectorate. The Inspectorate receives about 1500 complaints of patients about all healthcare sectors a year [32]. The following care providers are involved: medical specialist somatic care/hospital care, mental healthcare, inpatient elderly care, care for disabled persons, pharmacist, dental care, general practitioner, private clinic/independent medical centre, alternative care, paramedical care/rehabilitation, home care, child welfare care, forensic healthcare, emergency care, manufacturer/medical technology company, public healthcare, integrated care (cross-sectoral), and manufacturer medicines/pharmaceutical company. However, it is not the Inspectorate's statutory task to handle complaints from individual patients unless the complaints refer are structural or very severe [33]. The Complaint Act (introduced in 1995) requires all healthcare providers to install easily accessible independent complaint committees.

Previous research showed that patients' motivations for reporting their complaints to the Inspectorate are primarily to improve quality of healthcare and prevent the problem from happening to others. Furthermore, patients seemed to be aware of the fact that the Inspectorate is not there to handle individual complaints [21].

Methods

Selection of complaints

All complaints received by the Dutch Healthcare Inspectorate from the general public are recorded in a software program. Complaints received between 1 August 2012 and 31 October 2012 were studied, resulting in a total sample of 436 complaints. Complaints are usually made in writing (by letter, e-mail, or a standardised form on the Inspectorate's website). This document was regarded as the initial complaint and used for extracting data for this study.

Complaints made by professionals (often employees of a healthcare provider), complaints for the Disciplinary Board, complaints not about healthcare, or complaints in a language other than Dutch (because of the risk of interpretation difficulties) were excluded. This concerned 77 complaints. Five complaints were added to the dataset because the complaint letter included two different parts about different care providers. The final sample thus contained 364 complaints, including all healthcare sectors in the Netherlands.

Coding of the complaints

Additions to the taxonomy of Reader *et al.* were made firstly based on the researchers' knowledge of the field of work of the Dutch Inspectorate, and earlier research among complainants at the regulator [21].

Two raters (RB and an external rater) coded 364 complaints received by the Dutch Healthcare Inspectorate using content analysis. A detailed instruction for the raters was set up in order to obtain a homogenous assessment procedure. Extensive preparation of raters is widely acknowledged to be an important condition for a valid assessment process. Rater preparation included extensive discussion of the assessment framework, helping raters to recognise evidence and distinguish different categories [34]. The instructions and the taxonomy were first tested using 50 initial complaints. They were then adapted based on the experiences of the raters.

The remaining complaints were coded in three more sessions. The two raters assessed and coded the complaints independently. The raters made notes about themes that were difficult to code using the taxonomy and other problems that were encountered during coding.

After each session of coding, the percentage agreement and Cohen's kappa were calculated; differences were discussed by the raters and the category system was revised and adapted as necessary.

The taxonomy achieved its definitive form after coding of 162 complaints. The last 197 complaints were coded by the two raters using the final taxonomy. The first 167 complaints were then recoded by the two raters using the final taxonomy, and final kappa values were calculated.

Coding procedure

A fixed order for coding was provided to ensure that all categories were systematically considered. It was determined that a maximum of three themes per complaint could be encoded, as this was found to be a sufficient number of themes for most of the complaints. Montini *et al.* found that patient complaints averaged 1.5 codes, ranging from 1 to 9 codes per complaint [22]. Similarly, Reader *et al.* found an average of 1.49 issues per complaint, with a range of 1.05 to 3.19 [23]. Therefore, the maximum of three codes per complaint, taking into account our goal of an aggregated overview of complaints, seemed justified. Furthermore, this would keep the coding process and statistical calculations manageable. If a complaint contained more than three themes, it was coded as a 'complex

complaint'. Themes within complaints were coded using the order of the taxonomy; if applicable, first, themes within the clinical domain were coded, second themes within the relationship domain, and third themes within the management domain. Furthermore, the most specific categories within a domain were moved upwards within the taxonomy, so that the raters were encouraged to consider the more specific categories first.

Statistical analyses

Statistical analyses were conducted using STATA version 13. New variables were created to determine the frequencies (at least once) of the main categories within the complaints that each rater coded. Inter-rater reliability was analysed by calculating percentage agreement and a Cohen's kappa (κ) statistic for each main category. The kappa statistic is the most commonly used measure for reliability. The kappa was developed to adjust for guessing by raters, but the assumptions it makes about rater independence and other factors are not well supported. It therefore may lower the estimate of agreement. However if raters have had training and guessing is not likely to exist, presenting the two measures should be safe [35].

The following standard for interpreting the magnitude of kappa was used [36]:

≤ 0.0	Poor
0.01 – 0.20	Slight
0.21 – 0.40	Fair
0.41 – 0.60	Moderate
0.61 – 0.80	Substantial
0.81 – 1.00	Almost perfect

Frequencies of the main categories within complaints were calculated, whereby prevalent categories that were agreed upon in complaints were counted as 1 (i.e. a category is applicable to a complaint according to both raters); non-prevalent categories that were agreed upon were counted as 0 (i.e. a category is not applicable to a complaint according to both raters); and prevalent categories that were not agreed upon (i.e. a category is applicable according to one rater) were counted as 0.5.

Privacy

The complaint letters were encoded in the offices of the Inspectorate, in order to prevent further distribution of personal information of complainants. The raters signed a confidentiality agreement. Personal information about the complainants was not coded and not used.

Results

Characteristics of the complaints

Of the 364 selected complaints, 113 complaints (31%) were handled by the Inspectorate, 248 (68%) were not, with no information available for 3 complaints (1%). Most complaints were sent by e-mail (45%). About a quarter (27%) were sent using a specific form on the Inspectorate's website, and 24% of complaints were sent by letter. The remaining complaints were presented by phone or fax, or no information was available.

Examples of text fragments from complaints that were coded are shown in Box 2. The complaints often included multiple subjects.

Box 2 Examples of complaints

"The family does not receive adequate information about developments in good time, [...] medication is either not administered or it is done too late or incorrectly. [...] Staff are deployed for tasks for which they are untrained or not fully trained. [...] There is a structural shortage of skilled staff and they often work with flexible workers who have little experience in healthcare." (care for disabled persons) (*Subcategories involved: "medication errors", "insufficient or unqualified personnel" and "incorrect, incomplete, or missing information"*)

"While they were busy with the preparations, my wife was asked to sign a declaration [...]. Under the circumstances, she had no knowledge of the content of this declaration and had not been informed about possible complications. In the subsequent visit [...] I asked about the possible complications. They could not give us an answer." (private clinic, minor medical procedure to face) (*Subcategories involved: "incorrect, incomplete, missing information", and "consent"*)

"[...] I went to see my GP because of serious persistent stomach pain. A gastric acid blocker was subscribed. After various visits to my GP and keeping on insisting for four months, I was referred for colonoscopy. Colon cancer was diagnosed." (GP) (*Subcategories involved: "errors in diagnosis/triage"*)

The taxonomy

The original taxonomy of Reader *et al.* (2014) was adapted (see table 1 at appendix).

The final taxonomy consisted of 3 domains, 6 main categories and 29 subcategories, and a separate domain for complex complaints that included more than three themes. Table 1 shows the final taxonomy, where the symbols indicate changes made to the original taxonomy. Several specific reasons can be given for the adaptations made. Some subcategories were added to make the taxonomy applicable to care sectors other than hospitals, such as mental healthcare, pharmaceutical care and elderly care. For instance, a new theme that emerged in complaints by patients admitted to mental healthcare was “coercion and compulsory admission”.

Some main and subcategories were combined because they overlapped or because it was difficult for the raters to distinguish between the two themes. For instance, the subcategories of the two main categories ‘communication’ and ‘humaneness/caring’ in Reader’s taxonomy, were often overlapping. The same applied for ‘access and admission’ and ‘delays’. In addition, it was difficult for the raters to make a clear distinction between the main categories ‘quality’ and ‘safety’, which is also related to the multifactorial nature of the complaints.

Some domain and (sub)category names were reformulated to make them clearer and to reflect the underlying subcategories. For instance, the patients’ rights category was reformulated to cover human rights, because we concluded that complaints concerned not only patients’ rights but also fundamental human rights. Another example is the term “patient journey” in the taxonomy of Reader *et al.*, which appeared to be rather vague. This was reformulated into “coordination and alignment problems”.

Some (sub)categories were extended. For example, “medication errors” was extended to cover “medication” (i.e. not only medication errors but all kinds of problems with medication). In addition, “preference policy” was added to this subcategory (because insurers in the Netherlands determine which medication brands they reimburse, which means that patients may receive other medication brands from their pharmacists than they request and than they are used to). New themes that frequently emerged were added as new (sub)categories such as “inadequate record keeping” and “failure of equipment and materials”. Furthermore, a new subcategory “immoral/incorrect behaviour of the organisation or individuals within the organisation” was added to indicate cases of for instance

fraud, selling illegal medication, or illegal webshops.

Furthermore, several subcategories were added covering specific legislation that the Inspectorate supervises. For instance, the Inspectorate supervises compliance with the clients' right to complain Act, an Act that obliges care providers to provide an easily accessible complaints procedure for patients. A subcategory was therefore added, "insufficient compliance with legislation/regulations/protocols/guidelines and insufficient safeguarding of patients' rights". Another Act that the Inspectorate supervises is the Individual Healthcare Professions Act (wet BIG), which obliges all care providers to register in order to provide certainty about qualifications to practice their profession. The subcategory "title misuse" was therefore added.

Lastly, most descriptions of the subcategories were strengthened.

Inter-rater agreement and reliability of the taxonomy

Inter-rater agreement, reliability and 95% confidence intervals are shown for the final 197 complaints and the total number of 364 complaints that were coded with the final taxonomy (Table 2). The two 'other' main categories have been left out of the analysis, because those were scarcely used by the raters (6-10 times per rater per category). However, for use in practice it was considered to be useful to keep those categories in the taxonomy.

The mean kappa value at the level of the six main categories as calculated for the final 197 complaints coded using the final taxonomy was 0.61 (range 0.45-0.69). The final mean kappa value at the level of the six main categories as calculated for all 364 complaints was 0.64 (range 0.50-0.75). Kappa values of four main categories were deemed to be substantial. Kappa values of two main categories (communication and timing & accessibility) were seen as moderate. The mean kappa at the level of domains for all 364 complaints was 0.65 (substantial, range 0.61-0.69, 85% agreement avg.). The mean kappa at the level of subcategories for all 364 complaints was 0.56 (moderate, range 0.13-0.92, 95% agreement avg.). One rater assigned an average of 1.9 codes to each complaint; the figure for the second rater was 2.0. This means that on average 2 codes were assigned to each complaint. The "quality and safety" category was most prevalent (51%) in the complaints followed by "organisational and institutional problems" (38%) and "communication" (24%).

Table 2 Cohen's kappa, percentages for inter-rater agreement on the final 197 complaints coded using the final taxonomy and the total 364 of complaints and prevalence for each main category

N=364	Cohen's	%	Cohen's	%	%
Main category:	kappa	agreement	kappa	agreement	prevalence
	(95% C.I.) for		(95% C.I.)		
	final 197		total of		
	complaints		364		
			complaints		
Quality & safety	0.59 (0.47-0.70)	80%	0.62 (0.53-0.70)	81%	51%
Communication	0.45 (0.31-0.59)	80%	0.50 (0.39-0.60)	82%	24%
Human rights	0.63 (0.50-0.76)	88%	0.75 (0.66-0.83)	91%	21%
Organisational & institutional problems	0.66 (0.55-0.77)	85%	0.68 (0.60-0.76)	85%	38%
Timing & accessibility	0.69 (0.52-0.87)	95%	0.60 (0.46-0.74)	93%	9%
Complex complaint	0.66 (0.52-0.80)	90%	0.69 (0.58-0.79)	92%	16%
Mean	0.61	86%	0.64	87%	

Discussion

Internationally, attention for public participation and the use of complaints in healthcare quality regulation policies is increasing [1, 2, 12, 16-19]. Most existing complaint taxonomies focus primarily on hospitals [22, 23]. However, there are no taxonomies for analysing complaints in a wide array of healthcare sectors on an aggregated level for regulatory purposes. Analysis of complaint datasets by regulators would add to the range of regulatory tools used for monitoring and improving healthcare systems [20]. Furthermore, reporting of complaint data by regulators could contribute to the public accountability of regulators [20, 21, 37]. In this study, an existing taxonomy developed by Reader *et al.* (2014) was further developed and tested in order to provide a taxonomy applicable to eighteen different healthcare sectors and to encode and use patient complaints for

regulatory purposes in practice.

Reliability of the taxonomy

In contrast to other studies of complaints analyses, inter-rater reliability was calculated in this study for the domains, main categories and subcategories of the taxonomy. The average reliability on domain and main category level of the taxonomy was substantial. Four main categories were also classified as having substantial reliability. One category had a moderate kappa value (communication) and one category (timing & accessibility) had a nearly substantial kappa value. The mean kappa value at subcategory level was moderate, which may perhaps have been caused by the large number of subcategories [36].

Lower inter-rater agreement could be due to a lack of the knowledge or information needed for determining the subject of a complaint, or could depend on the backgrounds of raters. Assessment of complaints, notwithstanding extensive preparation, will always remain subjective [25].

Research into inter-rater reliability of adverse events analysis has shown that higher inter-rater agreements are found when assessments are based on explicitly defined criteria [24]. However, other authors who conducted analyses of complaints have argued that patients do not necessarily differentiate their experiences into separate clinical or relational components. It is often an interrelated cascade of problems that eventually leads to a complaint being lodged [22]. This was also seen in this study. Many complaints were multifactorial, unstructured and included multiple subjects which are also related to the diversity of the eighteen different healthcare sectors that were included. Defining strict criteria for the coding of the complaints was therefore difficult. This could be another factor contributing to the moderate kappa values.

It was decided to code a maximum of three categories within each complaint and code complaints with more than three codes as 'complex'. This might have pushed the complexity of patients' experiences to the background. These complaints might need retrospective in depth analyses in order to accurately explain and map the complex reality behind a complaint. However, in other studies, complaints averaged 1.5 code [22, 23], and given our goal of aggregately reporting complaints, it seemed legitimate to maintain a maximum of three codes.

Implications of the taxonomy for regulation

From the regulation and learning perspectives, merely recording complaints is of limited value. Standardised coding of patient complaints by regulators makes consistent and reliable documentation, analysis and reporting possible. Because of the three-level structure, aggregated analyses and more detailed (qualitative or quantitative) analyses at the subcategory level are possible. The taxonomy can for example be used for studying relationships between subjects in specific healthcare settings.

The taxonomy could serve as an instrument for regulators, transforming handling complaints from a regular compliance activity into opportunities for standardisation, international comparison, learning, and quality improvement [20, 23]. It could help regulators to respond more effectively to complaints and inform patients what impact their complaints have on quality of care [21]. A strength of this taxonomy is that it includes 'softer' or non-clinical aspects of caring that are important to patients, while taxonomies on adverse events are often limited to exclusively clinical aspects.

This study was confined to one sample of complaints. The collection of future samples provide an opportunity for future monitoring and pattern recognition of problems experienced by patients on healthcare sector, regional and national level.

For the use of the taxonomy for regulatory purposes, it is recommended that efficient ways should be found of assessing the urgency of the complaints so that action can be taken if required. In order to keep track of new emerging topics or specific problems that require rapid responses (e.g. PIP-implants) but that do not fall within standard categories, it is recommended that the taxonomy should be used dynamically and should be updated frequently.

Strengths and limitations

A strength of this study is that it draws upon previous research that supports theoretical and methodological development of this research base.

The taxonomy reached its final form after coding 167 complaints. Those 167 complaints were then coded again using the final taxonomy. The raters were already familiar with those complaints, which may have influenced the final kappa values. When calculating kappas, no account was taken of the fact that a maximum of three categories could be chosen. For each main category, we analysed whether the category occurred at least once in the complaints for each rater (yes-or-no judgement). Each main category was considered separately in the analyses,

completely independently of the other categories. If the maximum of three themes had not been set beforehand, it could be assumed that the raters would take each category and determine whether it applied to a complaint. This would mean that the calculated kappa values are overestimated. The addition of the “complex complaint” category partly overcomes this problem.

Complaints can be submitted to the Inspectorate in various ways: using a specific form on the Inspectorate’s website, by e-mail, or by post. However, the form on the website only allows a limited number of words. This meant that the length of complaint reports differed, and lengthier complaints were often more complex and difficult to code.

For practical and ethical (privacy) reasons, we were unable to highlight texts within the complaint letters and import them into a software programme for qualitative analyses. Nevertheless, it was possible to collect some relevant quotes from the complaints. Furthermore, no data was available on the type of care sector and the subjects of complaints on a yearly basis, which meant that we were unable to determine if the complaints used in this study are representative of a complete year.

Conclusion

An existing taxonomy for the analysis of complaints in healthcare was developed further into a taxonomy that is applicable to a wide array of healthcare sectors and for the use by healthcare quality regulators. The taxonomy appeared to be substantially reliable. An explanation for moderate kappa values could be that assessment of complaints is subjective and many complaints are multifactorial, unstructured and very diverse. In contrast with other patient safety studies focused on adverse events, this taxonomy is able to capture the ‘softer’ or non-clinical aspects of caring that are important to patients.

Standardised coding of patients’ complaints permits consistent and reliable documentation, which could help make regulators more accountable. The taxonomy could be used by regulators for analysing patients’ complaints, transforming this from a regular compliance activity into opportunities for learning, quality improvement and better patient satisfaction.

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Table 1 Final taxonomy, with symbols indicating the changes made to the original taxonomy

Domain	Category	Subcategory	Description
Clinical/care/ Cure ~	Quality and safety §	Incidents: Unforeseen and unintended event, not necessarily injurious; which is expected to not happen again ¶	<i>Incidents or complications that threaten patient safety (including failure of equipment, fall incidents)</i>
		Medication/medication errors/preference policy ¥	<i>Errors in prescribing or administering or prepare/offer medication, preference policy of insurers regarding medication</i>
		Errors in diagnosis/ triage/diagnostic assessment/medical judgement/assessing urgency §¥	<i>Wrong, missed or slow clinical diagnosis or judgment, inadequate identification of urgency. Inadequate diagnostic assessment</i>
		Inadequate record-keeping ¶	<i>Patient records not properly maintained, incomplete, incorrect, or lost</i>
		Failing equipment / material ¶	<i>Failures of equipment or materials</i>
		Title misuse ¶	<i>Misuse of professional title</i>
		Quality of care, skill and performance / improper or unprofessional behaviour / clinical treatment §	<i>Shortage of technical and non-technical skills of personnel to ensure safety (this includes addiction, illness). Bad or unsuccessful clinical treatment. Clinical or nursing care does not meet norms / standards</i>
		Coordination / alignment problems ~	<i>Problems in coordinating treatments between different departments / services by clinical staff</i>
		Other, namely ¶	

- Table 1 continues -

Domain	Category	Subcategory	Description
Relationship care provider- patient/comm unication ~	Communication §	Incorrect / incomplete / missing information /shared decision making §~	Communication of false, inadequate or conflicting information to patients
		Unprofessional response to complaint α	Unprofessional reaction by care provider when patient reveals complaint.
		Not listening, not taking patient seriously, rude attitude.§~	Impolite, disrespectful or insensitive behaviour toward patients. Bad attitude to patients and / or their family
	Human rights ~	Abuse/sexual misconduct ✕	Physical, sexual, emotional or financial abuse of patients (incl. between patients), or sexual misconduct
		Confidentiality	Break in confidentiality of patient or information
		Consent	Force or failure to obtain consent from patients
		Discrimination	Discrimination against patients
	Other α	Coercion and compulsory admission/BOPZ/RM α	The Psychiatric Hospitals (Compulsory Admissions) Act (Wet bijzondere opnemingen in psychiatrische ziekenhuizen, BOPZ)
		Other patient's rights and human rights α	Such as obligatory financial contributions, Social Support Act (WMO), cutbacks, personal budget (PGB), exceptional medical expenses (AWBZ)
		Other, namely	

- Table 1 continues –

Domain	Category	Subcategory	Description
Management / organisation / logistics / planning ~	Organisational and institutional problems ~	Immoral / incorrect behaviour of the organisation or individuals within the organisation α	<i>Such as fraud, selling illegal drugs, not having permits or certificates</i>
		Unhealthy, poor or unsafe environment / building or supporting services §~	<i>Poor accommodation, hygiene or food. Problems with support services such as visiting hours, reception, transportation</i>
		Finances, invoicing, billing, costs, patient's own contribution ¥	<i>Costs related to care, the bill or the billing process, own contribution, cutbacks, personal budget, patient's own contribution</i>
		Insufficient / unqualified personnel or (supporting) resources present ~	<i>Inadequate staffing and practical resources</i>
		Insufficient compliance with legislation / regulations / protocols / guidelines and insufficient safeguarding of patients' rights α	<i>Such as complaints committees not meeting deadlines laid down by law, failure to comply with the verdict of a complaints committee</i>
	Timing and accessibility	Inadequate organisation / logistics /bureaucracy /governance ~	<i>The entire organisation and logistics in an institution is bad, resulting in other problems. Problems with administrative policies and procedures), inadequate / no improvement in policy following indications (e.g. complaint)</i>
		People are not able to access or get admission to care or the care provider (or cannot do so in time) §~	<i>Inaccessibility of services or personnel, physical inaccessibility. Delay in admission or access to treatment, waiting / waiting lists</i>
		Discharge	<i>Too early, too late or unplanned discharge</i>
	Other α	Referral	<i>Problems with referrals</i>
		Other, namely	

- Table 1 continues -

Domain	Category	Subcategory	Description
Complex complaints ⌘	Complex complaints ⌘	Very complex problems that have existed at different moments or for a long time	<i>This category can be used when the complaint is so complex that more than three categories need to be ticked.</i>

~ Renamed /reformulated

\$ Combined

¥ Extended

⌘ New category

Chapter 5

Classifying patients' complaints for regulatory purposes: a pilot study

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Abstract

Objectives

It is assumed that classifying and aggregated reporting of patients' complaints by regulators helps to identify problem areas, to respond better to patients and increase public accountability. This pilot study addresses what a classification of complaints in a regulatory setting contributes to the various goals.

Methods

A taxonomy with a clinical, management, and relationship domain was used to systematically analyse 364 patients' complaints received by the Dutch regulator.

Results

Most complaints were about hospital care, mental healthcare, and elder care. About certain sectors such as emergency care, little numbers of complaints were received. The largest proportion of complaints concerned the clinical domain (51%), followed by the management domain (47%) and the relationship domain (42%).

In elder care, clinical domain complaints were more prevalent (65%), than in hospital care (56%), and mental healthcare (41%). In complaints about mental healthcare, the relationship domain was the most important (65%). The management domain was most prevalent in elder care (49%) compared to the other sectors.

Conclusion

Problem areas within different healthcare sectors could be identified by classifying the complaints. It provided insight in the regulator's own practices, which are aimed at public accountability. However, there are several limitations. Aggregated analyses were not possible in sectors with low numbers of complaints. Furthermore, the information remains rather superficial, and a standardized detailed system of reporting among agencies is needed. In order to assess which complaints need regulatory action, an in depth analysis, utilizing standardized methodology and criteria, of specific complaints is needed. Improving responses to patients requires more than merely aggregated reporting of complaints.

Introduction

In research, it is argued that current approaches to healthcare quality regulation tend to reflect a narrow clinical perspective that excludes the patients' perspective [1-6]. In addition, some large-scale incidents in several countries, such as the Mid Staffordshire NHS trust scandal, where patients signals were ignored, have further inflamed this debate [7, 8]. Regulators in various countries have therefore expressed a greater commitment to use patients' complaints [9-15].

There are differences between countries in what role complaints currently have in regulation. In Finland for example, patients can file complaints to the regulator who then judges the legitimacy of the complaint [16, 17], while in other countries such as the UK and the Netherlands, individual complaint handling is not the primary task of the regulator. Signals derived from individual complaints are often used to monitor the performance of individual care providers [9, 10, 18].

Internationally, researchers agree that aggregated analysis and reporting of adverse events including complaints of patients, by care providers and regulators is required [19-24]. Organizations could treat patient complaints similar to adverse events, by early detection, systematic analysis, learning and prevention of for instance malpractice risks [20, 25-27].

A recent study by Reader *et al.* (2014) therefore attempted to develop a taxonomy with the aim of classifying and reporting on patients' complaints at the hospital level [19]. According to the authors and other scholars, such aggregated analyses and classification of complaints would serve various goals. First, aggregated complaint analysis would give a chance to proactively identify (system-wide) problem areas that point to poor care and risk areas [19, 23, 28]. Secondly, it could help respond more effectively to individual patients and their complaints and give them a voice in regulation [19, 20, 22, 28, 29]. Thirdly, it could increase accountability of care providers and regulators to the government and the public for their actions [9, 23, 29].

Systematically classifying and analysing complaints by regulators is not common yet [9, 20, 29], while it would provide a first step towards using patients' complaints for regulatory purposes.

This pilot study therefore aimed to classify one sample of complaints about all healthcare sectors received by the Dutch Healthcare Inspectorate using a taxonomy. We aimed to explore what information can be extracted from a classification of complaints and to what extent this information contributes to the various goals.

The following study questions were formulated:

- Can problem areas be identified by classifying and aggregated reporting of a sample of complaints?
- Can classifying complaints help to respond more effectively to patients and their complaints and provide them a voice?
- How could classifying complaints contribute to public accountability of regulators?

The Dutch situation is used as a case study (more information Box 1).

Box 1 Information about the Dutch Healthcare Inspectorate

The Dutch regulatory system and complaints

In the Netherlands, the regulator of healthcare quality is the Dutch Healthcare Inspectorate. It is an independent part of the Ministry of Health, Welfare and Sports. The Inspectorate's policies are, as in many countries and different industries, based on the theory of responsive regulation of Ayres and Braithwaite (1992) [1]. This theory assumes that the relationship between the regulator and regulated parties is based on co-operation and trust. Regulation based on distrust would only lead to more penalties being imposed and therefore requires more capacity on the part of the regulator and ultimately leads to higher societal costs. Responsibilities are therefore first laid down at the regulated parties.

Information about the quality of care is analysed by the Dutch Inspectorate in order to signal potential risks. Information is collected in various ways including system-based supervision (monitoring of internal quality systems and governance arrangements), performance indicators, reporting of incidents (by the public or care providers), detection of prosecutable facts, and thematic supervision (selection of relevant themes which will be investigated further).

The Inspectorate receives about 1500 complaints annually from patients about all healthcare sectors [2]. However, complaints are only investigated by the Inspectorate if they meet the following specific criteria: severe deviation from the applicable professional standards by professional or other employees within the institution, severe failure or the absence of an internal quality system at an institution, severe harm to health or a high probability of recurrence of the problem. [3]. As in other countries, the Dutch Inspectorate was criticized in politics and by ombudsmen for failing to respond to patients and their complaints [4, 5], and has therefore stated a commitment to give a greater role to the patients' voice within its regulation policies [6].

Methods

Complaints selection

Complaints received by the Inspectorate between August 2012 and November 2012 were selected, resulting in a total sample of 364 complaints. Complaints made by professionals, about a sector other than healthcare, or written in a language other than Dutch were excluded. Complaints were received by letter, e-mail or through a digital form on the Inspectorate's website.

Systematic complaints analysis

A taxonomy was used to conduct a systematic content analysis and quantification of complaints. This taxonomy is based on the original taxonomy of Reader *et al.* (2014) [19]. This taxonomy was adapted to the Dutch regulatory setting and reliability was analysed in another study (Bouwman *et al.*, Submitted). Several reasons can be given for the adaptations made. Some main and subcategories were combined because they overlapped. Some domain and (sub)category names were reformulated or extended to make them clearer and to reflect the underlying subcategories. Furthermore, several subcategories were added making the taxonomy applicable to care sectors other than hospitals, such as mental healthcare and covering specific legislation that the Inspectorate supervises. For instance, the Inspectorate supervises compliance with the clients' right to complain Act, that obliges care providers to provide an accessible complaints procedure for patients. The taxonomy differentiates between the clinical (+ care, cure), management (+ organization, logistics, planning) and relationship (patient-care provider, communication) domains, which are grouped into 6 main categories (quality & safety, communication, human rights, organizational & institutional problems, timing & accessibility, complex complaints) and 29 subcategories. We tested the reliability of the taxonomy because the aim was that the taxonomy should be used in practice by the Inspectorate's employees of in order to encode complaints homogenously. The complaints were categorized and assigned into various taxonomy codes by two raters. The average reliability of the taxonomy at the level of main categories was considered substantial ($\kappa=0.64$). The mean kappa at the level of subcategories was moderate ($\kappa=0.56$).

Our goal of using the taxonomy was to create an aggregated overview of the subjects of complaints and workable system for complaint handlers for reviewing complaints from 18 health care sectors (i.e. hospital care, mental health and elder

care). Complaints from these sectors were classified into the three domains of clinical, relationship and management. Each domain was divided into main and subcategories of complaint themes (see Table 1). The content and themes in each complaint were analyzed and classified into a complaint subcategory in the appropriate domain. It was therefore determined that a maximum of three themes per complaint could be coded. Montini, *et al.* (2008) found that patient complaints averaged 1.5 themes, ranging from 1 to 9 themes per complaint [21]. Similarly, Reader *et al.* (2014) found an average of 1.49 issues per complaint, with a range of 1.05 to 3.19 [19]. The maximum of three therefore seemed justified. In addition, if it was not possible to assign a maximum of three themes to one complaint, it was encoded solely as a 'complex complaint'. Other information that was available to be extracted from the data was whether the complaint was investigated further by the Inspectorate, the type of care provider involved, and whether the complainant was the patient or someone else.

Table 1 List of the domains (**bold**), main categories (*italic*) and subcategories of the taxonomy

Clinical, care & cure domain
<i>Quality & safety</i>
Safety incidents
Medication/medication errors/preference policy
Errors in diagnosis/ triage/diagnostic assessment/medical judgement/assessing urgency
Inadequate record keeping
Failing equipment / material
Title misuse
Quality of care, skill and performance/ improper or unprofessional behaviour / clinical treatment
Coordination / alignment problems
Other, viz

- Table 1 continues -

- Table 1 continued -

Relationship patient-care provider domain

Communication

Incorrect/incomplete/missing information/shared decision making

Unprofessional response to complaint

Not listening, not taking patient seriously, rude attitude.

Human rights

Abuse/sexual misconduct

Confidentiality

Consent

Discrimination

Coersion and compulsory admission...

Other patient's and human rights

Other, viz

Management, organisation, logistics, planning domain

Organisational & institutional problems

Inappropriate / incorrect behaviour of the organization or individuals within the organization

Unhealthy, poor or unsafe environment / building or supporting services

Finances, invoicing, billing, costs, patient's own contribution

Insufficient / unqualified personnel or (supporting) resources present

Insufficient compliance with legislation / regulations / protocols / guidelines and insufficient safeguarding of patients' rights

Inadequate organization/ logistics /bureaucracy /governance

Timing & accessibility

People are not able to access or get admission to care or the care provider (or cannot do so in time)

Discharge

Referral

Other, viz

Very complex problems

Statistical analyses

Statistical analyses were conducted using the software program STATA version 13. New variables were created to determine the frequencies (at least once) of the domains, the main categories and subcategories within the complaints. To determine the frequency, occurring categories that were agreed upon in complaints were counted as 1 (i.e. a category is applicable to a complaint according to both raters), non-occurring categories that were agreed upon were counted as 0, and categories that were not agreed upon were counted as 0.5. A Venn diagram was constructed to assess the overlap of the three domains.

Types of care provider involved in the complaint classified by the two raters were compared. Only if differences were found, it was compared to the care provider type as initially classified by the Inspectorate itself. If one of the raters matched the classification of the Inspectorate, that type of care provider was chosen. If all three classifications mismatched, it was classified as 'unclear'. The same applies for whether the complainant was the patient or someone else.

Chi-squared tests were carried out to explore differences between numbers of complaints investigated further within healthcare sectors. Results were considered significant if $p < 0.05$.

Privacy

The complaint letters were encoded in the offices of the Inspectorate, in order to prevent further distribution of personal information of complainants. The raters signed a confidentiality agreement. Personal information about the complainants was not used.

Results

In order to explore what types of information can be extracted from classifying the complaints and what this contributes to the various goals, we analysed the complaints at different levels. We first analysed numbers of complaints per care sector. We then analysed the complaints at the domain, main category and subcategory levels of the taxonomy. For the three healthcare sectors with the highest number of complaints (hospital care, mental health and elder care), we conducted some more detailed analyses. In the discussion section, we will address how this information contributes to the various goals described in the introduction.

To illustrate the content of complaints patients reported to the Inspectorate, some text fragments from the complaints in the various care sectors are shown in Box 2. As can be seen, complaints are often complex and multifactorial and contain detailed information. On average complaint themes were categorized into two complaint subcategories.

Box 2 Fragments of complaints in different care sectors

"In the nursing home where my mother lived, the conditions are unhygienic. My mother's room smelled of urine, there was dust under the beds and the bathroom was filthy. [...] My mother's pressure sore was taken care of in this dirty room, on the dirty bedding. The care providers wore gloves but no aprons and they wore their hair loose. After two weeks, the wound was infected." (elderly care)

"While they were busy with the preparations, my wife was asked to sign a declaration [...]. Under the circumstances, she had no knowledge of the content of this declaration and had not been informed about possible complications. She signed the declaration in good faith. In the subsequent visit [...] I asked about the possible complications. They could not give us an answer." (private clinic, minor medical procedure on the face)

"My mum [...] slipped off the toilet. She pushed the alarm button and then had to wait for 15 minutes before someone came. [...] She broke her hip. It was decided (without consulting me) that X-rays were not needed. An operation is not seen as important because she cannot walk anyway." (elderly care)

"Tuesday-Wednesday-Thursday night: night shift staff are deployed who cannot assist with artificial respiration of a patient." (care for handicapped patients)

"I've heard that a fellow patient of mine has been in isolation for 5 months now. He is a vulnerable man who gets confused quickly. I blame it on clinic negligence because [...] the man was confused because of medication intoxication" (mental healthcare)

Complaints per care sector

Most complaints were about hospital care (22%), mental healthcare (17%), and elder care (12%) (Table 2). In half the complaints, the complaint was issued by the patient themselves. In 56% of the complaints about hospital care, the complaints were issued by the patient. In mental healthcare this was 67%. In elder care and care for disabled patients, almost all complaints (98% and 92%) were about someone else, who was mostly a relative. In total, 31% of complaints were investigated further by the Inspectorate.

Table 2 Care sectors the complaints were about, numbers of complaints that were investigated further by the Inspectorate, & number of complex complaints for each care provider

Care sector:	# complaints (%)	# further investigated	# Complex
Total	364 (100%)	113	57
Medical specialist somatic care / hospital care	79 (22%)	19	13
Mental healthcare	62 (17%)	11	10
Inpatient elderly care	44 (12%)	16	9
Other	28 (8%)	11	7
Care for disabled persons	27 (7%)	18	10
Pharmacist	24 (7%)	8	0
Dental care	18 (5%)	3	1
General practitioner	17 (5%)	5	2
Private clinic/independent medical centre	12 (3%)	5	2
Unclear	12 (3%)	2	0
Alternative care	7 (2%)	5	0
Associated care professions/rehabilitation	7 (2%)	1	1
Home care	7 (2%)	3	2
Child welfare care	7 (2%)	3	2
Forensic healthcare	6 (2%)	0	0
Emergency care	2 (1%)	1	0
Manufacturer/medical technology company	2 (1%)	2	0
Public healthcare	2 (1%)	0	0
Integrated care (cross-sectoral)	1 (0%)	0	0
Manufacturer of medicines/ pharmaceutical company	0	0	0

Complaints on domain level

Figure 1 shows a Venn diagram of the overlap between the three domains of the taxonomy. The clinical and relationship domains have the greatest overlap (14%), followed by the clinical and management domains (13%). All three domains overlap in 8%. Furthermore, the relationship domain occurs alone least often (9%) in the complaints.

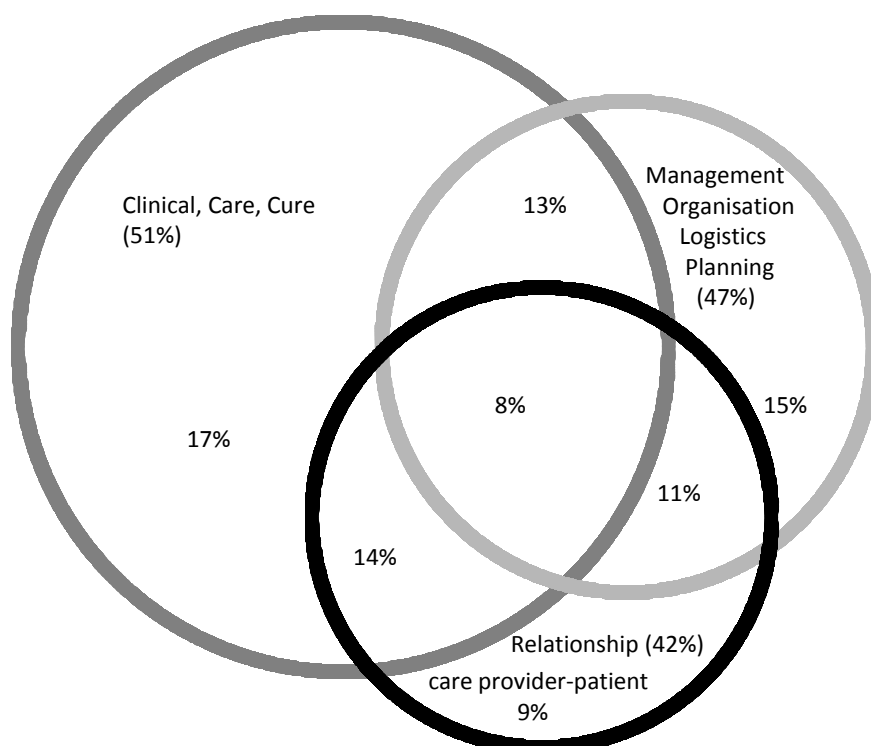


Figure 1 Venn-diagram of the overlap of the three domains

To gain insights into the regulator's decisions about complaints, we analysed the number of complaints investigated for each domain of the taxonomy (Figure 2). More information about the current process for determining which complaints to investigate can be found in Box 1. Within the clinical domain, significantly more complaints were investigated (37%, $p=0.02$) by the regulator compared to the other categories (26%-30%).

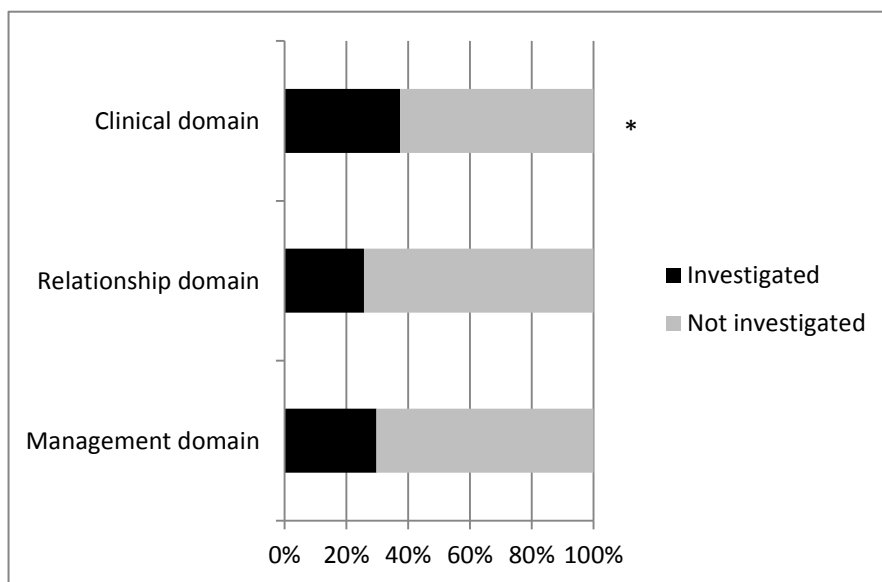


Figure 2 Percentages of complaints investigated and not investigated per domain

* Significant difference between complaints that concern the specific domain compared to the complaints that concern the other domains, $p\text{-value} < 0.05$ (far right column)

Complaints at the main category and subcategory levels

Figure 3 shows the distribution of the complaints over the six main categories and 29 subcategories. Of the 364 complaints, the largest proportion concerned the main category “quality & safety” (187, 51%). Within this main category, the subcategories that were most prevalent were “quality of care, skills and performance, improper or unprofessional behaviour or clinical treatment”, and “safety incidents”.

Almost four out of ten (138, 38%) complaints concerned the main category “organizational & institutional problems”. Within this main category, the most prevalent subcategories were “inappropriate/incorrect behaviour of the organization or individuals within the organization”, and “unhealthy, poor or unsafe environment/building or supporting services”. Only a small proportion within the management domain concerned the main category “timing and accessibility” (34, 9%).

Communication issues were present in about a quarter of the complaints, of which the most were about “incorrect/ incomplete/missing information/shared

decision making” and “not listening, not taking patient seriously, rude attitude”.

Within the category “human rights” (77, 21%), “coercion & compulsory submission” was the most prevalent subcategory, followed by “abuse/sexual misconduct”.

Complaints issued by the patients themselves were significantly more often about human rights compared to complaints issued by someone else. For the other main categories, no significant differences were found.

Complaints on domain level in three sectors with most complaints

For the three healthcare sectors with the highest number of complaints (hospital care, elder care and mental health), differences in the occurrence of the domains were analysed (Figure 4). The clinical domain occurred in all sectors, but significant differences were found ($p=0.006$). In elderly care, it was more prevalent (65%) than in hospital care (56%) and mental healthcare (41%). In mental healthcare, the relationship domain occurred significantly more often (65%, $p=0.008$) than in the other sectors. These complaints mostly concerned human rights issues. The management domain was most prevalent (49%) in elder care, this was not significantly different from the other healthcare sectors. In figure 5, absolute numbers of complaints for each domain in the three healthcare sectors are shown. It is also shown how many of those complaints were investigated further by the Inspectorate, to see in detail what decisions were made by the Inspectorate. In mental healthcare, in total, fewer complaints (18%) were investigated than in hospitals (24%) and elder care (36%) but this did not differ significantly. In general, relatively more complaints within the clinical domain were investigated, and these mostly concerned safety and abuse or sexual misconduct (not in Figure).

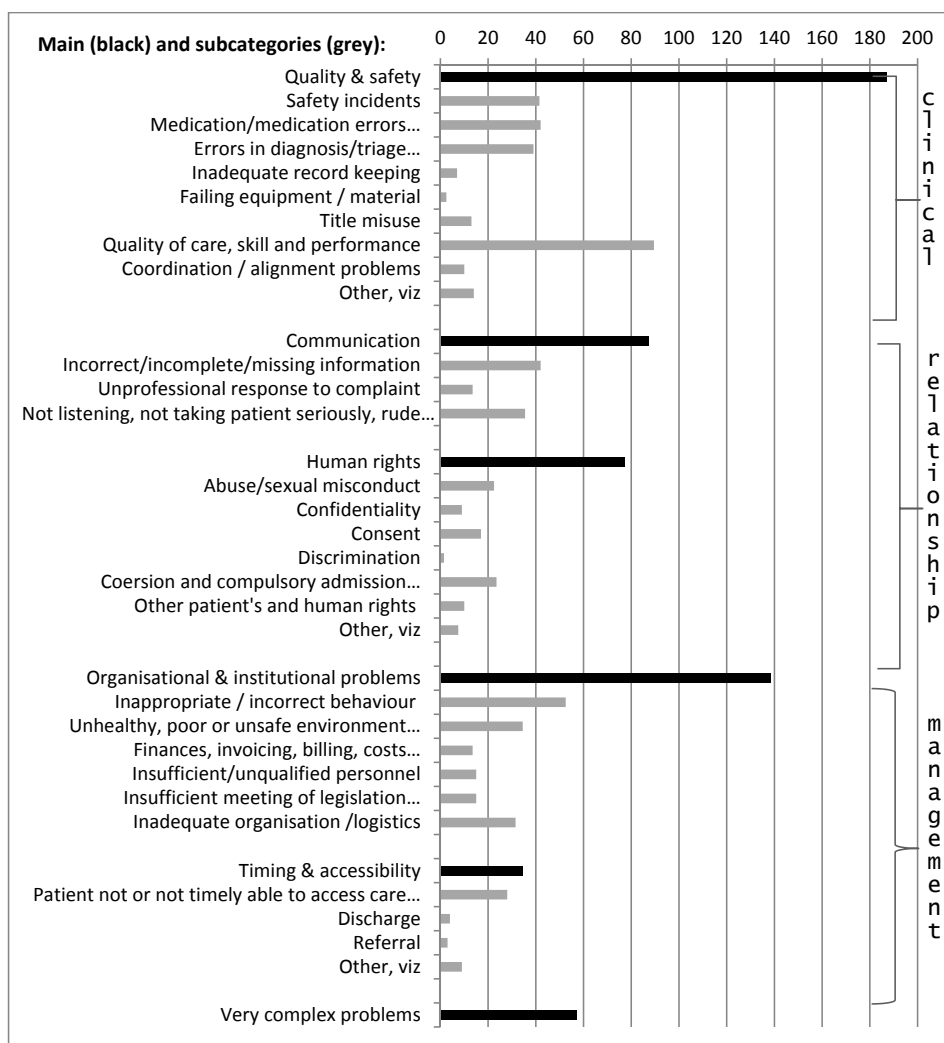


Figure 3 Absolute numbers of occurrences of main categories and subcategories within the complaints, divided into the three domains

* the number of the complaints that concern a specific subcategory may not add up to the exact number of complaints in the main categories because they were included if the main category was present at least once in the complaints, while up to three different subcategories could be encoded.

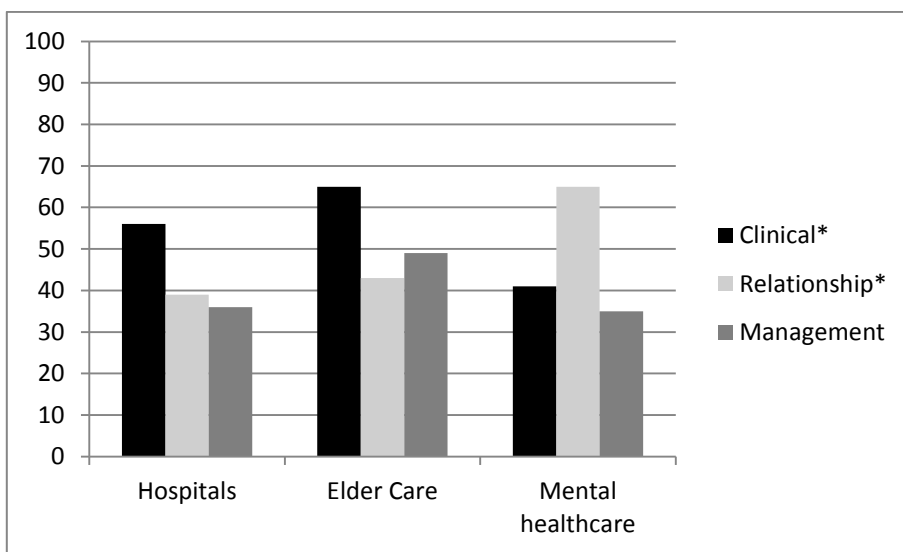


Figure 4 Percentages of occurrence of domains within the complaints in three sectors with most complaints

* significant difference ($p < 0.05$) between the three domains (far right column)

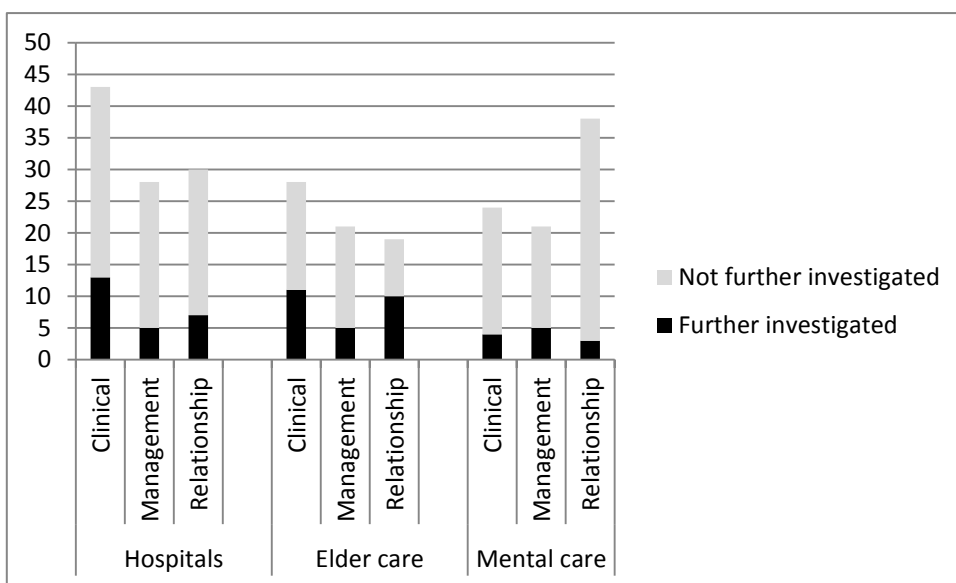


Figure 5 Absolute numbers of complaints in each domain for each healthcare sector and numbers of further investigated complaints

Discussion

In this pilot study, a sample of patients' complaints received by the Dutch Healthcare Inspectorate was classified using a taxonomy that was adapted from Reader *et al.* to the regulatory setting. From a regulatory perspective, we examined what information can be extracted by classifying and quantifying the complaints and whether this information meets the goals that were set in the literature. The results are discussed with reference to those goals [9, 19, 20, 22, 29].

Identifying problem areas and quality and safety issues

Classifying complaints makes it possible to structure and document the often complex and unstructured complaints into interpretable and easy-to-report categories. The analysis provided information at a national level and care sector level.

This pilot study was confined to one sample of complaints received by the Dutch Healthcare Inspectorate within three months, providing a first step towards creating a central overview of complaints. At the national and care sector level, it was possible to identify problem areas. Slight shifts of patterns were seen in the problems that patients reported in different healthcare sectors. The patterns were quite clear for characteristics of the cure and care sectors. For instance, in elder care, patients point to organizational problems more often than in other sectors. However, identifying problem areas and patterns is only possible if sufficient numbers of complaints are received for each sector. For instance, in home care and emergency care, too few complaints were received for this analysis. Moreover, assuming that complaints reported by patients are only a 'tip of an iceberg', we cannot be sure that the complaints reported are representative for all patients' experiences in healthcare.

Furthermore, the classification supports basic analyses, but does not accurately explain and map the complex reality behind a complaint. The information that the analysis provided remains rather superficial. This makes it difficult to assess which complaints need regulatory action. Important details and contextual information described in the complaints are crucial for determining the severity of a complaint. The same phenomenon has already been described in the case of incident reporting: while the main principle of reporting incidents was to identify and prioritize significant risks, in practice incidents are only counted in order to monitor performance of care providers, removing the opportunity for broader learning [30,

31]. Classification of complaints can be seen as a first step, helping to set priorities. The second step would be analyses of the content of complaints that were selected in the first step in-greater depth. Furthermore, helping the learning processes requires not only classifying and quantifying, but also social processes involving the regulators, complaint investigative agencies and care providers.

Giving patients a voice

The analysis gives insights into what aspects of healthcare are relevant for improving healthcare quality, according to the patients. It provides contextual information allowing further consideration of how to incorporate patients' perspectives into healthcare quality regulation. Formally, the Inspectorate further investigates patients' complaints if they point to severe or structural problems [32]. The results show that only a selection of complaints, often including a clinical component, are investigated further by the Inspectorate. However, other research has shown patients have different perceptions of the relevance of their complaint for healthcare quality [29]. Furthermore, as observed in other studies, patients have differing views about factors relating to healthcare quality and safety [33, 34]. Patients often assess the care received on a broad spectrum of aspects going beyond exclusively clinical markers, such as the interpersonal skills of the care provider [35] and how care is organized [36].

If regulators want to give patients a voice and use complaints in their work, they may therefore need to broaden their perspective of the factors that contribute to healthcare quality.

Responding to complaints

Patients' dissatisfaction with responses to their complaints is often associated with an expectation gap [29, 37-39]. Other research shows that patients find it important to prevent the problem from recurring by reporting their complaint to a regulator. They want to be kept informed about the effect of their complaints on quality of care. However, they lack confidence in the effects their complaints have [29]. It would therefore seem that mere aggregated reporting of complaint data is insufficient to meet the patients' expectations. The aggregated overview of complaints could be used for publicly reporting what effects complaints have on the healthcare system [20, 29, 40]. However, a clearer understanding of the expectation gaps that arise between complainants and regulators is still needed in order to achieve solutions that improve responses to complaints and patient

satisfaction.

Increasing public accountability

This study provided an opportunity to gain insight in the regulator's own practices and recognize its own blind spots. It creates a bigger picture of which complaints are selected by the Inspectorate for further investigation and which not. Quality issues were investigated more often by the Dutch regulator, which is in line with its statutory task [32]. However, differences are seen between the healthcare sectors in the numbers of complaints investigated. Furthermore, some themes and subjects that patients reported, such as safety incidents and abuse, are addressed more frequently than others. This information could help in making evaluation procedures and decisions more homogenous and consistent, and improve public accountability. The Inspectorate could consider whether it is desirable that certain subjects are not addressed.

It is also interesting to consider the results in the context of other complaint investigative agencies and organizations. One interesting finding is that the Inspectorate received complaints about elder care, while other research has shown that patients in elder care hardly ever lodge complaints [22, 41]. They do not want to be seen as 'difficult' [41]. The Inspectorate is, thus, perceived to be more accessible by patients in elder care than other complaint options.

There will still be an important challenge, as clarification is needed about the most appropriate roles for care providers, complaint investigative agencies and regulators regarding the monitoring of and responding to complaints.

Future research

With our relatively small study sample, we were not able to conduct more complex analyses. A further study should examine whether future follow-up samples of complaints allow for comparisons over time that point to emerging problems as experienced by patients. Furthermore, it is recommended that other information sources are linked to the aggregated complaint data, such as numbers of incidents reported by care providers. This will allow patterns of non-reporting to be detected and more precise comparisons between the performance of different care providers to be made. In other research, it has been shown that different reporting systems such as incident reporting, risk management reports, patient complaints and malpractice claims, all produce substantially different, incomplete but complementary pictures of patient safety. Under-reporting is a major issue, as

sometimes 95% of adverse events are not reported [42]. Systems for achieving a detailed understanding of the full range of things that go wrong at the population level are largely undeveloped [23].

Additionally, the predictive value of complaints could be further studied in order to clarify the value of using complaints for regulatory purposes [25, 27]. Examples: the relationship between complaints and mortality rates, incidents, patient satisfaction or regulatory measures against care providers could be analysed [43].

Strengths and weaknesses

A unique aspect of this study is that it includes complaints about various healthcare sectors, while other studies on complaints often focus on one sector, which is mostly the hospital sector [19, 39, 44].

A strength of this study is that an evidence-based and substantially reliable taxonomy was used.

No basic characteristics such as age, gender and ethnicity, of the complainants were available, because they were hard to extract from the often unstructured complaint data.

It should be noted that classifying complaints is a labour-intensive activity. Furthermore, future analyses using the taxonomy require extensive rater preparation and practice as this is widely acknowledged to be an important precondition for a valid assessment process in content analysis [45].

Conclusion

This pilot study reveals that a complaints classification makes it possible to structure and document the often unstructured complaints into interpretable and easy-to-report categories. If complaint numbers are sufficient, the classification allows problem areas within different healthcare sectors to be identified. It also gives insights into the regulator's own practices and blind spots, which could help the regulator's public accountability. The overview of complaints could also be used for publicly reporting what effects complaints have on the healthcare system.

However, there are several limitations on meeting the goals that are targeted by a complaints classification. Because the classification reduces the complexity of the complaints, the information remains rather superficial. In order to assess if the

complaints need regulatory action, an in-depth analysis of emerging issues is still needed. All complaints should have detailed standardized information. Detailed information about the severity of the complaints, may show a severe lapse in safety, which may be enough to initiate a policy change. Associated to this, criteria for which complaints are eligible for investigation should be clearly set. However, without some form of standardized reporting of complaints, there is no way to monitor what patients experience in healthcare and give them a more consolidated voice in the regulatory practice. Standardization of detailed complaint information should promote sharing between complaint investigative agencies and stimulate learning processes.

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Chapter 6

Is there a mismatch between the perspectives of patients and regulators on healthcare quality? A survey study

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Abstract

Objectives

Internationally, healthcare-quality regulators are criticized for failing to respond to patients' complaints. Patient involvement is therefore an important item on the policy agenda. However, it can be argued that there is a discrepancy between the patients' perspective and current regulatory approaches.

This study examines whether a discrepancy exists between the perspectives of patients and regulators on healthcare-quality.

Methods

A questionnaire was sent to 996 people who had registered a complaint with the Dutch Healthcare Inspectorate in order to measure expectations of and experiences with the Inspectorate. A taxonomy was used to classify the nature of their complaints into the clinical, relationship or management domains.

Results

More complaints about clinical issues (56%, $p=0.000$) were investigated by the regulator than complaints about organizational (37%) and relational issues (51%). Patients with complaints about management issues less often indicated (13%, $p=0.002$) that healthcare is improved by making their complaint than patients with complaints about clinical or relationship issues did (22-23%). Patients who reported about relational issues with care providers attached more importance to issuing sanctions against the care provider than other patients (avg score 2.89 vs. 2.62-2.68, $p=0.006$).

Conclusions

The predominant clinical approach taken by regulators does not match the patients' perspective of what is relevant for healthcare quality. In addition, patients seem to be more tolerant of what they perceive to be clinical or management errors than of perceived relational deficiencies in care providers. If regulators want to give patients a voice, they should expand their horizon beyond the medical framework.

Introduction

Several countries such as New Zealand, the UK and the Netherlands are facing problems with public trust in healthcare quality regulation [1-5]. It is argued that current patient safety approaches tend to reflect a narrow medical perspective that excludes the patients' perspective, creating a discrepancy between the two [6-11]. In addition, some large-scale incidents such as the Mid Staffordshire NHS trust scandal, where patients complaints were not responded to, have further inflamed this debate [5, 12]. When evaluating that case, it was recommended that openness and transparency about concerns must be ensured and that a greater role should be given to complaints within the regulatory process [13]. The Care Quality Commission has expressed a commitment to pay more attention to patients' complaints in its regulation policies [14]. In other countries, similar developments can be seen. Regulators have expressed a greater commitment to improving responses to complaints and giving patients a greater voice [4, 13-17].

However, if regulators want to involve patients and their complaints in their policies, a clearer understanding of the discrepancies between the two perspectives that seem to arise is needed, either in terms of issues that are considered relevant or in terms of providing information on the effects of reporting a complaint. This could help create solutions that improve responses to complaints and patient satisfaction.

This study examines if there are discrepancies between the perspectives patients and regulators and what they imply. We studied to what degree the evaluation procedures and responses of a regulator to complaints of various natures ((clinical (e.g. related to purely medical subjects) and non-clinical (e.g. related to organizational or relational subjects)) presented by patients match the patients' perspectives on the relevance and perceived effects of their complaints. Complaints received by the Dutch healthcare quality regulator (more information in Box 1) are used as a case study.

We aim to answer the following questions:

- Is there a difference in patients' expectations of a regulatory authority between patients with complaints that are clinical and non-clinical in nature?
- Which complaints (clinical and non-clinical in nature) are considered to be relevant by the regulator for further investigation and improvement of healthcare quality and does this match the patients' perspective?
- How do patients with clinical and non-clinical complaints perceive the effects of their complaints on healthcare quality and does this match their expectations?

Box 1 information about complaints about healthcare in the Netherlands

The Dutch Healthcare Inspectorate is mandated by the Ministry of Health, Welfare and Sports to regulate and monitor healthcare quality. It is not the statutory task of the Inspectorate to handle complaints by individual patients. Other research already showed that patients are aware of that [18]. Responsibility for handling of patients' complaints lies primarily with the care providers, where patients can complain directly at complaint officers or boards. Complaints are only eligible for further investigation by the Inspectorate when complaints point to structural or very severe problems. The criteria are severe deviation from the applicable professional standards by medical professionals or other employees within the care institution; severe lack or failure of an internal quality system at a care institution; severe harm to health; a high probability of recurrence; or when care providers do not comply to the Clients' Right to Complain Act [19]. This Complaints Act obliges care providers to install easily accessible independent complaints committees. The aim of such a committee is to focus explicitly on the legitimacy of the patient's complaint. Research has however shown that many patients are dissatisfied after this procedure [20].

The Inspectorate receives approximately 1500 complaints annually from patients of which the majority are not investigated further by the Inspectorate, given its remit [21]. However, it was argued that the Inspectorate does not take patients seriously, and should value patients' complaints as signaling deeper problems [5, 12, 22-24]. It was stated in political debates that the patients and their complaints deserve more attention and should be involved in regulatory policies in order to reflect patients' perspectives [12, 22, 23]. In order to improve responses to complaints, an independent contact point for the general public was set up in order to guide patients with complaints.

Methods

This study draws upon newly collected data and data and instruments used in previous research [18]. A taxonomy was used to determine the nature of the complaints. Furthermore, we submitted a survey to patients who reported complaints to the Inspectorate, to measure their expectations and experiences with reporting their complaint. Information about which complaints were investigated further by the Inspectorate gave us insights into the relevance of complaints for healthcare quality from the regulator's perspective.

Selection of the study population

A survey was sent to all people (996) who submitted a complaint to the Inspectorate between August-November 2012 or between April-August 2013. The selection of two different periods was helpful in preventing contextual factors (such as media exposure after incidents) having too much influence on patients' perceptions of the Inspectorate. Furthermore, numbers of respondents to analyze differences between subgroups within the study population would be sufficient.

Several inclusion criteria were formulated:

- The complaint must have been submitted by a member of the public/patient (or relative), not a care provider
- The complaint must be about healthcare (so general questions or complaints about the Inspectorate itself were excluded)
- If a complaint was further investigated by the Inspectorate, the investigation of the Inspectorate had to be closed, and the complainant had to have been informed about the closure by letter, so as to minimize the risk of respondents assuming that their response would have an impact on the handling of their complaint.

An employee of the Inspectorate ensured the complaints met the inclusion criteria.

Two reminders were sent. After those, the response rate was 44%. An abridged survey was therefore sent to non-responders.

In total 67 respondents dropped out because their addresses were incorrect, the person had moved, or was deceased. 33 people who filled out the survey were left out of the analyses because they were included in a special intervention by the Inspectorate in which extra attention was given to the complainant, which may have influenced their experiences when reporting the complaint.

The survey

The design of the survey about complaints was driven by the theory of procedural, distributive and interactional justice [25]. Information about the development of the survey can be found elsewhere (see reference) [18].

The survey comprised three parts: (1) characteristics of the person and complaint (subject and severity of physical injury); (2) people's expectations when reporting to the Inspectorate; and (3) experiences with reporting. An open answer option was given to elucidate the subject of the complaints. Severity of any physical harm caused was measured on a five-point-scale (1=no physical- 5=death). The questions were in the form of statements for which respondents could indicate the importance of the specific statement. Immediately afterwards, respondents were asked how much they felt that these statements actually applied (experiences). Respondents' expectations making the complaint (from 'not important' to 'most important'), and experiences with the reporting (from 'no' to 'yes') were measured on four-point scales [18].

Taxonomy

A taxonomy was used to conduct a content analysis of the complaints. This taxonomy was developed and reliability analyses were conducted for it in another study, using another complaint sample than used in the current study. The earlier study aimed to develop a standardization technique for complaint analyses covering all healthcare sectors and the setting of regulation.[Bouwman, Bomhoff, Robben, Friele; submitted]. The taxonomy differentiates between the clinical/care/cure domain, management/organization/logistics/planning domain, and patient-care provider relationship/communication domain. Those domains are used for grouping 6 main categories and 29 subcategories. The average reliability of the taxonomy, analyzed by using the ratings of two raters, at the level of the main categories was substantial ($\kappa=0.64$). The taxonomy is given in the appendix.

The answers of the respondents to the questions and the open answer options about the nature of the complaints were used to classify each complaint within up to three domains, main categories and subcategories of the taxonomy (by the first author). This means that up to three domains, main categories and subcategories can apply to one complaint.

Statistical analyses

Statistical analyses were conducted using the software program STATA version 13. Background characteristics of the study population were compared against the characteristics of the Dutch population [26] and are presented descriptively. Prevalence of the domains, main categories and subcategories was analyzed by counting whether they occurred at least once within the complaints. A Venn diagram was made to show the overlap between the domains. Differences in severity of physical injury between the two groups (complaints that were/were not investigated) and scores of importance of expectations between the three domains were calculated using t-tests. Percentages of which expectations were actually met (experiences) according to the respondents were calculated by adding scores 3 and 4 together for each variable. Differences in those experiences between the three domains, plus some detailed analyses of the subcategories of the taxonomy, were calculated using chi-squared tests. The expectations and experience items were split across three scales, based on a factor analysis conducted in a previous study [18]. Differences were considered significant if $p < 0.05$. Cases with missing values were left out of the analyses.

Ethics statement

The study protocol was presented to an external Medical Research Ethics Committee which concluded that formal ethical approval for this study was not required under Dutch law, as the study does not involve a medical intervention (METC protocol no. 13-018/C). Privacy was guaranteed because research data and personal information of respondents were kept separate. Surveys were sent by the Dutch Inspectorate by post. It was stressed that it could be returned anonymously to the first author. It was explicitly stated that their individual answers would not be revealed to the Inspectorate. The first author kept a list of respondent codes that were also printed on each survey and the Inspectorate kept a list with the same codes and the associated names and addresses. This allowed response rates to be monitored and reminders to be sent to non-responders by the Inspectorate. The lists were destroyed after 6 months.

No personal information or medical information of the respondents was used in this study.

Results

First, we describe the background characteristics of respondents, types of care providers and the nature of the complaints, plus the severity of physical injury related to the complaint. We then focus on what the respondents expected of reporting their complaints to the Inspectorate, and if differences exist depending on the nature of the complaint. After that, we describe which complaints were relevant for further investigation by the Inspectorate, and how the respondents with complaints of various natures experienced those responses by the Inspectorate.

Background characteristics of respondents and nature of their complaints

The response was 54% (N=503, (51% excluding 33 respondents who were included in the intervention)). Basic study population characteristics are shown in Table 1. More than half of the respondents were female. Relatively more respondents were aged 40–64 than in the Dutch population at large. The study population consisted of relatively highly educated people.

Table 1 Background characteristics of the respondents compared to the Dutch population

	N (Respondents)**	%	Dutch population (aged 18 and older) 2013 % ^[26]
Gender	353		
Female	134	62%	51%
Male	219	38%	49%
Age	353		
18-39	45	13%	34%
40-64	221	63%	45%
65 and older	87	25%	21%

- Table 1 continues -

- Table 1 continued -

	N (Respondents)**	%	Dutch population (aged 18 and older) 2013 % ^[26]
Educational level	342		
Low (none, primary school or pre-vocational education)	87	25%	30%*
Middle (secondary or vocational education)	97	28%	40%*
High (professional higher education or university)	158	46%	28%*
Unknown	-	-	2%

* These percentages applied to the Dutch population aged 15 to 65 in 2012.

** The total number of respondents may differ because some respondents did not fill out all questions or only completed the short survey.

Table 2 shows the types of care that the complaints were about. Most complaints concerned hospital care (23%), nursing homes (18%) and mental healthcare (18%). A relatively large proportion of complaints concerned the 'other' answer option (20%). Examples of the answers are occupational doctors, haptonomist and ambulance services.

Table 2 type of care the complaints are about and absolute numbers of complaints investigated further within the care sector

Type of care complaint is about	# complaints N=363	# investigated
Hospital care	84 (23%)	25
Nursing homes/residential care	67 (18%)	35
Mental healthcare	65 (18%)	19
Drug therapy	38 (10%)	8
General practitioner	35 (10%)	10
Medical technology	35 (10%)	18
Care for the disabled	31 (9%)	15
Dental care	33 (9%)	15
Private clinic	19 (5%)	8
Home care	13 (4%)	4
Community care	7 (2%)	0
Physical therapy	2 (1%)	1
Other	72 (20%)	28

What patients find relevant for healthcare quality

Figure 1 shows the total number of complaints reported by patients per domain. The clinical domain occurred most often (64%) and overlapped almost equally with the other two domains. The management and relationship domains were present in four out of ten of the complaints, with a mutual overlap of 7%. Only 4% of all complaints were about all three of the domains. To illustrate a complaint about the clinical domain, a patient described a safety incident as: “Got a metal on metal hip. [...] Had high concentrations of cobalt and chromium in my blood.” To illustrate a complaint about the relationship domain, a patient described a complaint about communication: “Insufficiently informed by attending physician [...] about possible consequences of placing a prosthesis.”

An example of a complaint about the management domain is: “Admitted as a heart patient in the weekend. Unit was left unstaffed because of staff shortage.”

No significant differences were found in the prevalence of the domains within the complaints with regard to age, gender and educational level (not in Table).

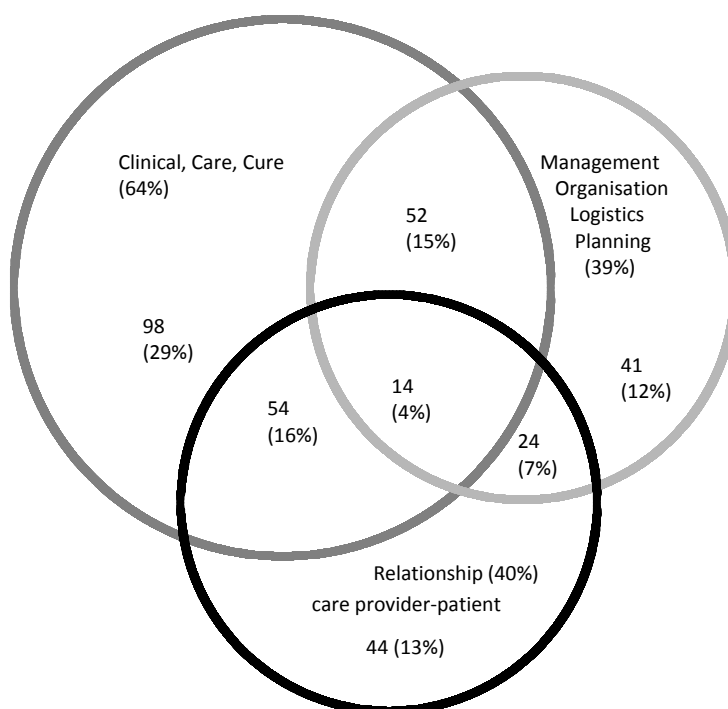


Figure 1 Venn diagram of distribution of domains occurring in the complaints reported by patients (excluding complex complaints (4%))

Patients' expectations of the inspectorate

Table 3 shows the average scores of importance for patients' expectations when reporting complaints, given separately for the three domains. For most respondents it was most important that reporting their complaints leads to benefits in terms of quality of care.

Patients with complaints in the relationship domain had significantly higher expectations of specific consequences for the care provider in question compared to the other two domains ($p=0.006$). They felt it is important that the inspectorate should have a hard-hitting conversation, and that the care provider should be punished or banned from working. Detailed analyses showed that especially patients who reported about care providers not listening/not taking seriously, about rude attitudes or abuse found it more important that sanctions should follow compared to the remaining patients (not in table, $p=0.000-0.02$).

Table 3 Average scores of importance for specific outcome expectations and scale-scores distributed over the three domains

	Importance scores for each domain:		
	Clinical domain	Relationship domain	Management domain
Expectations:**			
I made my complaint to the Inspectorate because I wanted...	N=179-207	N=113-132	N=110-124
Benefits for quality of healthcare in general	3.52	3.58	3.52
the care institution to learn from my complaint	3.39	3.51	3.49
to prevent it from happening to others	3.61	3.70	3.56
to improve the quality of healthcare	3.51	3.58	3.56
to improve the safety of healthcare	3.51	3.51	3.51
Personal benefits	2.68	2.89*	2.62
to restore my sense of justice	2.72*	3.15*	2.64*
a solution to my problem	2.81	3.01	2.78
to prevent it from happening to me again	2.82	2.84	2.79
the damage/harm to be repaired	2.41	2.72*	2.36
Specific consequences for care provider	2.51	2.70*	2.43
financial compensation for the damage/harm to be offered	1.87	1.96	1.63*
the care provider in question to be banned from working	2.22	2.50*	2.10
the inspectorate to have a hard-hitting conversation with the care provider in question	2.79	3.03*	2.78
the care provider in question to be punished	2.04	2.47*	2.04
the department of the care institution to be closed	1.58	1.73	1.65
to do my duty by making a complaint	2.89	3.04	2.75*

* significant difference between complaints that involve at least the specific domain compared to the complaints that do not.

** The expectations were divided into three scales (benefits for quality of healthcare in general; personal benefits; specific consequences for care provider) based on a factor analysis conducted in a previous study.¹⁸

Relevance of the complaints according to the Inspectorate

In order to analyze what relevance in terms of healthcare quality the Inspectorate assigned to complaints, we distinguished two groups within the sample: patients whose complaints were investigated further by the Inspectorate (n=185, 39%) and those whose complaints were not (n=285, 61%). No significant differences were found between the average score of self-reported severity of physical injury in investigated (2.5 avg.) and non-investigated complaints (2.3 avg.).

Figure 2 shows the total number of complaints for each single domain and those overlapping two or three domains, and the number of investigated complaints. Most complaints concerned the clinical domain, and a greater proportion of clinical complaints were investigated by the Inspectorate (56%, $p=0.000$, not in table) than in the relationship (41%) and management domains (37%).

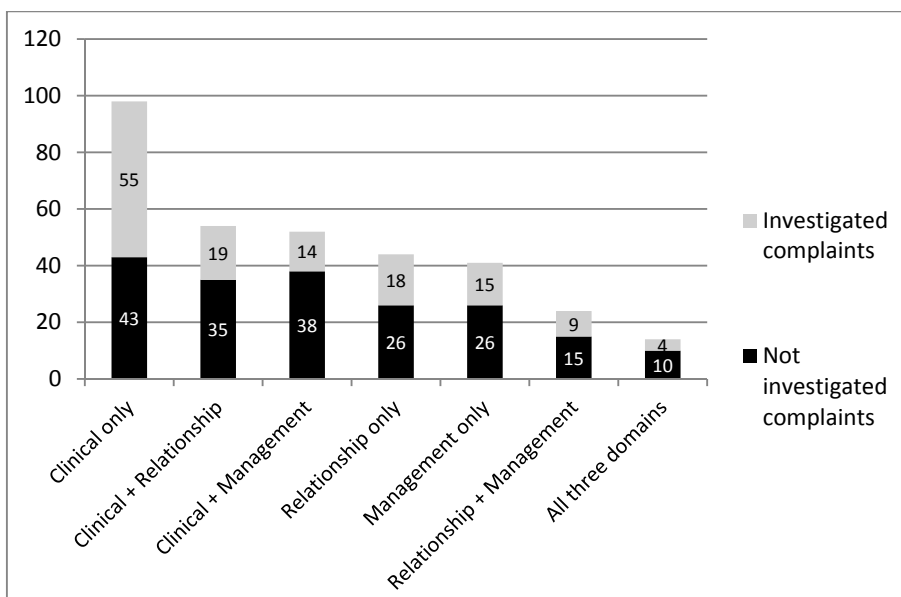


Figure 2 total number of complaints for each single domain, number of complaints overlapping two or three domains and number of investigated complaints

In addition, the average score of severity of physical injury in complaints about the clinical domain was significantly higher (2.8, $p=0.001$, not in Table) than in the other domains. In-depth analyses of the subcategories showed that complaints

coded as safety incidents and title misuse were investigated significantly more often than the other complaints ($p=0.001-0.05$, not in table). Figure 2 also shows that fewer complaints were handled when a complaint concerns a second and/or third domain besides the clinical, or when it concerns exclusively the relationship or management domain (or both of those).

Patients' experiences with the inspectorate

Table 4 shows the experiences patients had with reporting their complaint and the responses of the Inspectorate. For the items on the benefits for quality of healthcare, patients complaining about management issues reported significantly fewer positive experiences compared to the other patients ($p=0.002-0.01$). Detailed analyses show that these effects mostly concern complaints about finances, inappropriate behavior, insufficient/unqualified personnel, and insufficient compliance with legislation/directives ($p=0.01-0.04$).

Positive experiences are obviously related to whether complaints are investigated: patients with complaints that were investigated more often report that their complaint led to benefits for quality of care ($p=0.000-0.005$, not in table).

Table 4 (scale) percentages of experiences of complainants, distributed over the three domains. Items were measured on a four-point scale (no to yes). Percentages presented in this figure are based on scores 3 and 4 of each variable.

Experiences:**	Clinical domain	Relationship domain	Management domain
Making my complaint to the Inspectorate led to...	N=167-194	N=103-119	N=99-116
<i>Benefits for quality of healthcare in general</i>	23%	22%	13%*
...the care institution having learned from my complaint	22%	24%	17%
...the same thing being prevented from happening to others	29%	26%	15%*
...the quality of healthcare being improved	23%	23%	13%*
...the safety of healthcare being improved	25%	22%	13%*

- Table 4 continues -

- Table 4 continued -

Experiences:**	Clinical domain	Relationship domain	Management domain
<i>Personal benefits</i>	14%	13%	12%
...my sense of justice being restored	18%	20%	16%
...my problem being solved	15%	15%	16%
...the same thing being prevented from happening to me again	22%	20%	14%
...the damage/harm being repaired	5%	5%	4%
<i>Specific consequences for care provider</i>	22%	23%	18%*
...financial compensation for the damage/harm being offered	2%	3%	3%
...the care provider in question being banned from working	11%	8%	9%
...a hard-hitting conversation being held with the care provider in question	18%	18%	11%
...the care provider in question being punished	8%	10%	6%
...the department of the care institution being closed	8%	6%	7%
...doing my duty by making a complaint	79%	80%	72%

* significant difference between complaints that involve at least the specific domain compared to those that do not.

** The experience items were divided into three scales, based on a factor analysis conducted in a previous study [18].

Discussion

This study examined whether there are discrepancies between the perspectives of patients and regulators and what those imply. We focused on what relevance regulators and patients attach to complaints of different natures, what patients with different complaints expected of the regulator, and how the regulator reacted to different complaints.

Mismatch between what patients and regulators find relevant for healthcare quality

Formally, the Inspectorate further investigates patients' complaints if they are severe or point to structural problems in healthcare [19]. However, this study shows divergence in the criteria playing a role in what the Inspectorate considers relevant. Complaints with a clinical component are more often the subject of further investigations by the Inspectorate, while management and organizational problems, such as insufficient or unqualified personnel or non-compliance with legislation, seem to be less relevant to the Inspectorate when assessing problems encountered by patients. However, according to patients, a broader scope of aspects of quality of care are relevant and can be learned from. This illustrates the mismatch between the 'biomedical' agenda of medico-legal bodies and 'life-world' agendas of patients [27] and refers to what is an ongoing discussion in research; the medical model being dominant and a leading determinant in constructing or reconstructing the context of medical harm, adverse events, complaints and patient safety [7-11, 28]. It has often been argued that the current definition of medical harm excludes the non-disease-specific or non-clinical aspects that the patient may consider harmful [7, 8, 11]. In fact, patients often evaluate the care received on non-clinical aspects, such as the interpersonal skills of the care providers [29] and how care is organized [30]. Furthermore, what constitutes an adverse event according to patients refers not only to the original event but also to a broader array of aspects such as the aftermath of the event and how they were treated [7].

These experiences suggest that if the regulators do want to give patients a voice in their policies and acknowledge the patients' perspective, a broader perspective should be adopted rather than relying heavily on a narrow medical model or letting the 'clinical view' dominate.

Regulator responds less effectively to patients who reported organizational issues

The results show that patients with complaints about organizational aspects felt less often that their complaint had an effect on quality of care. This is obviously explained by the fact that fewer complaints about organizational issues are investigated further by the Inspectorate. However, no differences were seen between the nature of the complaint and the relevance for quality of care that patients attached to their complaint. Patients therefore seem to think that there is also a learning potential from organizational problems for care providers and the

regulator.

Bismark (2015) argues that medico-legal agencies are often focused too much on handling complaints in a procedurally correct way [31]. The results seem to fit with this reasoning; complaints about organizational issues do not seem to fit in the established processes and procedures of the Inspectorate, which could limit effective responses to patients, really hearing their voice and providing what they need.

Furthermore, it could be questioned why organizational problems are deemed to be not structural and considered less relevant for the quality of care by the Inspectorate. In addition, patients may have a better view of these types of problems in healthcare than regulators do during for instance regulatory visits and inspections.

Surprising results about expectations when complaint concerns relational deficiencies

For most patients, regardless of the nature of their complaint, it is most important that their complaint has an effect on healthcare quality. Personal benefits or consequences for care providers are less important. Nevertheless, unexpected but interesting differences are observed regarding the nature of complaints, and what patients want from reporting their complaint to the regulator. Patients with complaints that concern relational capabilities of care providers attach more importance to sanctions against the care provider in question than other patients do. Furthermore, this study shows that those patients find it very important that their sense of justice is restored. These findings are similar to what was found in other studies. Research has shown that communication subjectively perceived by patients as unsatisfactory was the main factor that made them decide to initiate legal proceedings [32]. Levinson *et al.* [33] found that physicians who received no complaints were those who provided information, asked the patient's view, and used humor.

Research among the Dutch public showed that the majority agree with a soft approach of imposing measures by regulators in cases of poor quality of care [34]. However, patients thus seem to be less tolerant of perceived relational deficiencies of care providers than of what they perceive to be clinical or management errors [29]. Regulators could take this into account when inviting patients to report their complaints and manage their expectations if they approach them. It could additionally be debated whether regulators should play a role in addressing care

providers in cases of relational deficiencies. Lastly, these results could be an important indicator for care providers that they should be aware of their relational (and in particular listening) skills. And, openness, apologies and appropriate action after adverse events are essential to patients [35,36].

Strengths and limitations

A strength of this study is the large sample size.

The response rate in this study was modest, even after sending two reminders and an abridged survey. There is therefore a risk of response bias. One consequence could be that the results of this study are not fully representative of the group of people who complained to the regulator. Non-response analysis was not possible because no characteristics of the non-respondents were available, in part due to the meticulous privacy arrangements. Research shows that non-respondents are more likely to be members of minority groups and lower educated groups [37]. No characteristics were available of the respondents who returned the abridged survey either.

Some respondents indicated that completing the survey made them uncomfortable because it revived the situation that the complaint was about. This could be an important reason for the non-response. Another reason could be that filing the complaint itself had already cost a great deal of effort, making people reluctant to participate. The study population is older and more highly educated than the general Dutch population. This might be explained by the fact that this specific group feel more empowered to complain to the regulator.

The complaints were classified using the taxonomy by only one author, do to time constraints. Therefore, there could be a risk of misclassification bias. Nevertheless, the taxonomy has already shown to be substantially reliable.

It is unclear whether the results of this study also apply to other regulatory authorities. This requires further research.

Conclusion

There is a mismatch between the patients' and the regulator's perspectives. Whereas the clinical view dominates in the regulator's perspective, patients believe that a broader scope of contextual, organizational and relational aspects of quality of care is relevant. This clinical view limits effectively responding to patients by the

Inspectorate, really hear the patients' voices and provide what they need.

The nature of complaints affect patients' expectations from reporting their complaint to the regulator. Patients are less tolerant when their complaint concerns relational deficiencies in care providers than when they perceive it to be a clinical or management error. It could be debated whether regulators should play a role in addressing care providers for their relational deficiencies. Furthermore, these results could be an important indicator for care providers that they should be aware of their relational skills (in particular listening to patients).

To conclude, if regulators want to include the patients' perspective in their policies, they should expand their horizon taking account of the needs and expectations of patients, rather than relying too much on the medical model.

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Appendix taxonomy used in this study for content analysis of complaints with percentages of distribution of complaints (N=340)

Domain	Category	Subcategory	Description
Clinical/care/ Cure (64%)	Quality and safety (64%)	Incidents: Unforeseen and unintended event (not necessarily injurious) which is expected to not happen again (8%)	<i>Incidents or complications that threaten patient safety (including fall incidents)</i>
		Medication/medication errors/preference policy (10%)	<i>Errors in prescribing or administering or preparing/offering medication, preference policy of insurers regarding medication</i>
		Errors in diagnosis/ triage/diagnostic assessment/medical judgement/assessing urgency (7%)	<i>Wrong, missed or slow clinical diagnosis or judgment, inadequate identification of urgency. Inadequate diagnostic assessment</i>
		Inadequate record-keeping (1%)	<i>Patient records not properly maintained, incomplete, incorrect, or lost</i>
		Failing equipment / material (4%)	<i>Failures of equipment or materials</i>
		Title misuse (2%)	<i>Misuse of professional title</i>
		Quality of care, skill and performance / improper or unprofessional behavior / clinical treatment (23%)	<i>Shortage of technical and non-technical skills of personnel to ensure safety (this includes addiction, illness). Bad or unsuccessful clinical treatment. Clinical or nursing care does not meet norms / standards</i>
		Coordination / alignment problems (3%)	<i>Problems in coordinating treatments between different departments / services by clinical staff</i>
		Other, namely (1%)	

Domain	Category	Subcategory	Description
Relationship care provider- patient/comm unication (40%)	Communication (31%)	Incorrect / incomplete / missing information /shared decision making (11%)	<i>Communication of false, inadequate or conflicting information to patients</i>
		Unprofessional response to complaint (3%)	<i>Unprofessional reaction by care provider when patient reveals complaint.</i>
		Not listening, not taking patient seriously, rude attitude. (11%)	<i>Impolite, disrespectful or insensitive behavior toward patients. Bad attitude to patients and/or their family</i>
	Human rights (11%)	Abuse/sexual misconduct (5%)	<i>Physical, sexual, emotional or financial abuse of patients (incl. between patients), or sexual misconduct</i>
		Confidentiality (2%)	<i>Breach of confidentiality of patient or information</i>
		Consent (2%)	<i>Force or failure to obtain consent from patients</i>
		Discrimination (0%)	<i>Discrimination against patients</i>
	Other patient's rights and human rights (0%)	Coercion and compulsory admission/BOPZ/RM (3%)	<i>The Psychiatric Hospitals (Compulsory Admissions) Act (Wet bijzondere opnemingen in psychiatrische ziekenhuizen, BOPZ)</i>
			<i>Such as obligatory financial contributions, Social Support Act (WMO), cutbacks, personal budget (PGB), exceptional medical expenses (AWBZ)</i>
		Other, namely (0%)	
	Other (0%)		

Domain	Category	Subcategory	Description
Management / organization / logistics / planning (39%)	Organizational and institutional problems (35%)	Inappropriate / incorrect behavior of the organization or individuals within the organization (7%)	<i>Such as fraud, selling illegal drugs, not having permits or certificates</i>
		Unhealthy, poor or unsafe environment / building or supporting services (6%)	<i>Poor accommodation, hygiene or food. Problems with support services such as visiting hours, reception, transportation</i>
		Finances, invoicing, billing, costs, patient's own contribution (10%)	<i>Costs related to care, the bill or the billing process, own contribution, cutbacks, personal budget, patient's own contribution</i>
		Insufficient / unqualified personnel or (supporting) resources present (3%)	<i>Inadequate staffing and practical resources</i>
		Insufficient compliance with legislation / regulations / protocols / guidelines and insufficient safeguarding of patients' rights (5%)	<i>Such as complaints committees not meeting deadlines laid down by law, failure to comply with the verdict of a complaints committee</i>
	Timing and accessibility (4%)	Inadequate organization / logistics / bureaucracy / governance (7%)	<i>The entire organization and logistics in an institution is bad, resulting in other problems. Problems with administrative policies and procedures), inadequate / no improvement in policy following indications (e.g. complaint)</i>
		People are not able to access or get admission to care or the care provider (or cannot do so in time) (3%)	<i>Inaccessibility of services or personnel, physical inaccessibility. Delay in admission or access to treatment, waiting / waiting lists</i>
		Discharge (0%)	<i>Too early, too late or unplanned discharge</i>
		Referral (1%)	<i>Problems with referrals</i>
		Other, namely (0%)	

Domain	Category	Subcategory	Description
Complex complaints (4%)	Complex complaints (4%)	Very complex problems that have existed at different moments or for a long time (4%)	<i>This category can be used when the complaint is so complex that more than three categories need to be ticked.</i>

Chapter 7

General Discussion

In a number of countries, regulators have been criticized after high-profile incidents in healthcare where patients' complaints were not addressed [1-4]. As a result, there has often been a political debate about the high expectations society has of regulators, and calls for stricter supervision and more attention to patients' complaints from regulators have often been expressed by the media [5-7]. Regulators in various countries in different sectors have therefore expressed greater commitment to involving the public more in their regulatory policies and improving responses to complaints [1, 7-12]. This is in line with broader international trends of democratization in healthcare [13, 14].

Little research has been performed on the expectations and perspectives of the public about regulation of healthcare quality. Evidence from a very small body of research suggests that the public has other views and expectations of the role of the regulator concerning health and safety risks than governments or healthcare professionals [15, 16]. This means that it is important to know what their view entails and what is implied if regulators want to involve the public and patients more in their work.

This thesis therefore assesses the discrepancies and similarities between the values and expectations of the different voices within the public domain, and the theories, concepts, policies and practices of healthcare quality regulation. This knowledge is needed in order to effectively align the regulators' and public's perspectives, and to assess different approaches for involving the public in regulation policy. Furthermore, the results of this thesis could help regulators respond more effectively to individual patients with complaints.

The studies were carried out in the Netherlands, where the Dutch Healthcare Inspectorate is responsible for healthcare quality regulation. In the studies, different populations were approached using various methods in order to gain more understanding about the public's and patients' perspectives and compare them to the regulator's responses to patients and the public. Questions about general concepts and theories underlying regulation policies were submitted to a sample of respondents who were representative of the general Dutch population. Furthermore, interviews were conducted and a questionnaire was submitted to a sample of people who had reported a complaint about healthcare to the Dutch Healthcare Inspectorate. Lastly, we performed content analyses on the complaints submitted by those people using a taxonomy designed for this study. This gave various insights in the public's perspectives on differing aspects of regulation and quality of care.

Main findings

There are differences between the perspectives of the public and patients and that of the regulator. These differences were found on various dimensions. The perspectives can be grouped along four dimensions:

1. Quality of care
2. Responsibilities for healthcare quality
3. Regulatory policies and strategies and their effects on quality of care
4. Expectations of individual patients when reporting their complaint and the responses of the Inspectorate

The differences between the perspectives for each dimension may provide important insights and reveal various fundamental implications for healthcare quality regulators who are considering involving patients and the public more in their work.

The results will be reflected upon, referring to the differences between patients and the regulator on the four dimensions. For each dimension, the theoretical assumptions and principles will be discussed first. Subsequently, the results of the studies will be described and placed in the context of other research. Finally, policy implications for each dimension will be suggested.

1. Dimension: quality of care

The principles behind patient participation in the evaluation of healthcare quality

As described, the Inspectorate made a fundamental decision to involve the public's/patients' perspective more in the evaluation of healthcare quality. Several 'pragmatic' assumptions have been made about the involvement of the public and patients in healthcare quality regulation. People are expected to participate actively in the public services they use, voicing their preferences and perspectives so that the services can respond to their needs [5]. In addition, public participation may have advantages that complement the current quality of information resources and may safeguard against the limitations and blind spots of those resources [6, 7, 8]. Participation mechanisms allow regulators to expand their supervision by using the public as a source of information and as agents for change [17].

There are also some more theoretical assumptions about involving the public's and patients' perspectives in the evaluation of healthcare.

An important theory that many regulators use for designing and developing their policies and strategies is the theory of responsive regulation [18]. This theory provides guidance about how the relationship between regulator, regulated parties and other stakeholders should be configured and how the regulator can determine which measures should be taken in cases of very poor quality. An important component of the theory of responsive regulation is 'tripartism', a democratic approach to regulation. In tripartism, a public interest group participates as a third group in the regulatory process, alongside the regulator and the regulated party: it is given power by being granted access to all the information that is available to the regulator, and by being offered a seat at the negotiating table for enforcement and compliance. It is proposed as a mechanism for empowering public interest groups and preventing conflicts of values between the different stakeholders [18-22]. Furthermore, it is assumed that giving the public a role means regulatory capture can be prevented [23, 24]. As regulators primarily interact with the party they supervise, 'regulatory capture' may easily lie ahead unnoticed; the term means that there is less of a separation between the regulator and the regulated party. The regulator is 'captured' in the sphere of influence of the regulated party, and the public's interest could drop out of sight. This sometimes makes it difficult for the regulator to take firm measures [25]. The idea is that effective regulatory design involves other stakeholders such as patients and consumers, rather than treating the relationship with the regulated party as exclusively bilateral. When consumer interests are clear and articulable, they may provide relevant information and different perspectives that help counteract the regulated party's influence [24].

Results for the patient's perspective of what quality of care constitutes

Content analyses of complaints show that a broad scope of aspects contribute to quality of care, according to patients.¹ Complaints by patients relate to clinical, management/organizational, and relational aspects of care. Many complaints made by patients were multifactorial, unstructured and included multiple subjects. However, complaints with a clinical component are investigated further relatively far more often by the Inspectorate, whereas management and organizational problems, such as insufficient staff numbers or unqualified personnel or non-

¹ See results in chapters 5 and 7

compliance with legislation seem to be less relevant to the Inspectorate when assessing quality of care.

Another important observation is that slight pattern shifts were seen in the problems that patients reported in different healthcare sectors. The patterns were quite clear for characteristics of the 'cure' and 'care' sectors. In elderly care for instance, patients point to environmental and organizational problems more often than in other sectors. In hospital care, clinical issues such as diagnostic errors are reported more often. These findings seem logical at first, but when thinking about patient participation and designing participation mechanisms, policymakers should be aware of the different aspects that are relevant to patients admitted in different care sectors.

Results in the context of theory and other research

Our study illustrated a difference between the regulator's and patients' perspectives on what constitutes quality of care.² The results reflected what is often discussed in other research: the differences between the 'biomedical' agenda of medico-legal agencies and the 'lifeworld' agendas of patients [26]. It has often been argued that the current definition of medical harm excludes non-disease-specific or non-clinical aspects that the patient may consider harmful [27-29]. In fact, patients often evaluate the care received on the basis of non-clinical aspects, such as the interpersonal skills of the care providers [30] and how care is organized [31].

The biomedical model is often dominant and a leading determinant in constructing or reconstructing the context of medical harm, adverse events, complaints and regulating patient safety [27-29, 32-34], while for patients a broader context plays a role. If regulators are considering approaches for involving patients, these are important insights that should be taken into account.

A small but growing body of research about public participation in regulatory policies gives important directions for how participation works out in practice. There seem to be pitfalls and difficulties when involving the public in regulation policies.

Conflicts between perspectives of regulators and the public are sometimes perplexing. A study experimenting with involving patients as mystery guests showed that inspectors did not use the information delivered by the mystery guests because the way they evaluated quality and reported the findings did not

² See results in Chapter 6

match with practices used by the Inspectorate [8].

Another study by Rutz *et al.* in which adolescents were involved in policies of the Dutch joint Inspectorate for Youth and Youth Care found that the adolescents' perspective was not only supplementary but also conflicted with the inspectors' perspective. In the latter case, which may be more likely to happen in highly ambiguous situations, the participation process became also more difficult in practice [Rutz, S., van de Bovenkamp H., Buitendijk S., Robben P., de Bont A. Submitted]. The same was also seen in a study on involving the public in local safety projects for reducing crime and disorder, a different regulatory area. One of the problems observed was a mismatch between expectations and perspectives between the general public and professionals. People felt discouraged by bureaucratic issues that policy officers tend to erect in order to maintain their neutral role, and to let them do their work consistently and correctly. In addition, minority groups and other less privileged residents were comparatively underrepresented in the communal safety projects [35].

Implications for the Inspectorate

It seems that the existing quality standards and frameworks that policy officers and inspectors use to assess quality in practice do not leave enough room for the public's and patients' perspectives.

The Dutch Healthcare Inspectorate monitors the quality of care using medical standards frameworks and assesses quality of care using professional guidelines or standards, developed by the professional field itself. Matters raised by patients are not necessarily cases where the professional standard is at stake. Here we have two different and not necessarily overlapping standards frameworks: the patient's and the regulator's. In other words: the patient's reality does not always equal the inspectorate's reality with regard to healthcare quality. If regulators want to incorporate the patients' perspective, the definition of quality of care used for regulation practices might not be wholly applicable and may differ for different (care and cure) healthcare sectors. They need to think about that different perspective and what it means to incorporate it in current regulation policies. It may lead to different standards frameworks, based on what patients find important. Processes may need to be arranged differently and it might require a paradigm shift on the regulator's side.

But, according to the theoretical assumptions, the existing differences between perspectives of patients and those of regulators on healthcare quality could be a

good reason to involve them in the first place. Including the different perspectives of patients may lead to disruption of the regulator's routinely acquired picture as proposed with 'tripartism' and may therefore prevent regulatory capture [24].

More research is needed about what does and does not actually work, taking into account both the patients' and regulators' perspectives.

2. Dimension: responsibilities for healthcare quality

Principles and policies of responsibilities for regulation

As described, the theory of 'responsive regulation' is an influential theory that many regulatory policies are based on. The basic idea of this theory is that the parties being regulated are considered to be trustworthy and intrinsically motivated by social responsibility. This vision is often described as 'high trust, high penalty' [18]. Regulation based on distrust would lead to more sanctions, more capacity requirements for the regulator and higher costs. Responsibility is therefore initially given to the regulated parties. This strategy corresponds to the international trend of government functions changing from the old "commanding and controlling" to "steering not rowing", whereby responsibilities are shifted from the government to the field and new governing mechanisms are introduced such as marketization of public sectors [5, 36-38].

These are also ongoing trends in the Netherlands. Since the introduction of the Quality Act (1996) in the Netherlands, care providers have been given more responsibilities and are supposed to develop quality standards. These responsibilities also include handling individual complaints from patients about healthcare. The Dutch Healthcare Inspectorate is an independent part of the Ministry of Health, Welfare and Sports and is mandated to supervise and regulate healthcare quality. The Inspectorate supervises compliance with obligations imposed by legislation, assuming that care providers have an intrinsic motivation to act rationally and in a socially responsible way, according to the theory of responsive regulation.

Results for the patients' perspective on responsibilities

To assess what the public's views are on the distribution of responsibilities for quality, we presented them with several actors in healthcare and asked them to

rank them by how responsible they are for the quality of care.³ For comparison purposes, the same was asked for quality of food and quality of education. The regulator was reckoned to have the most responsibility for quality of care by the majority of the Dutch general public. Next in ranking came the care providers, the minister, managers, colleagues of care providers, and finally the European Union. Patients were rated as bearing the least responsibility for quality of healthcare.

The same results were seen for quality of food and quality of education in this study: the public placed the regulators at the highest position with regard to responsibility for quality. Furthermore, the bulk of the public assigned a high degree of responsibility to the groups actually carrying out the work in the three sectors such as care providers, teachers and food preparation personnel. Students and their parents in the educational setting and consumers in the food service industry were seen as the least responsible for quality in the sector.

Most people thus seem to consider the regulator as a powerful authority. From the studies that involved patients with complaints, the results point in the same direction. Many complainants indicated that they had already lodged their complaint somewhere else before reporting to the Inspectorate [39]. If they see no options for conciliation, patients may deliberately address their complaint to the regulator, who they expect to stand up for them. Patients who experienced problems in the relationship with their care provider in particular were seeking justice and wanted the care provider in question to be sanctioned.⁴ Patients thus seem to be less tolerant of perceived relational deficiencies of care providers than of what they perceive to be clinical or management errors [30] and they might see the regulator as a powerful authority that corrects care providers and thereby maintains justice.

Results in the context of theory and other research

With regard to responsibilities for quality of care, the ideas of the public differed from current underlying theories and concepts of regulation.

The results of our studies showed that the majority of the Dutch general public partly support the idea of 'high trust, high penalty' from the theory of responsive regulation, as they attributed a high degree of responsibility to care providers. However, fundamental discrepancies between the perspectives of patients and regulators also became apparent from the studies: the predominant rhetoric of

³ See results in Chapter 2

⁴ See results in Chapter 6

decentralization of the responsibilities of regulators was not supported.

There is a generalized idea among much of the public that the state regulator has a prominent role, as same patterns were observed regarding responsibilities in the healthcare, food and education sectors.

The studies also show a kind of ambivalence among the public towards their own role in regulating healthcare quality. On the one hand, a study showed that the majority of people support public participation in regulation policies [40]. On the other, patients and the public considered themselves to bear least responsibility for the quality of care.⁵ The same results were seen in this study for quality of food and quality of education: the majority of the public placed themselves on the lowest position with regard to responsibility for quality.

This ambivalence is also seen in other research [41]. When everything goes well and it is business as usual, people do not expect much government interference. The public seem to endorse the principle of their own responsibility and want to be left free in what they do. But they choose government responsibility in concrete or 'risky' situations, when they are not well informed and/or when they are (emotionally) involved [42]. For instance, they want on the one hand that "more should be left to the people themselves" but also want criminality to be tackled by the government. To quote Bouttellier, "Do not stand in my way, but discipline my neighbour", or "Take care of me, but watch out for the others" [43].

Policy implications: active patients?

The results about the public attributing themselves a restricted role in the responsibility for the quality of healthcare contrast with the goals of the reform of marketization in healthcare towards more 'active patient choice', more responsibility for patients and democratization in healthcare.

Other research also showed that implementing concepts such as active patient choice and involving patients in decision-making processes in practice seems to be difficult [44, 45].

For instance, a study on how the assumptions about active patient choice turn out in practice shows that comparative information seems to have a relatively limited influence on the choices patients make. Patients base their decisions on a variety of characteristics of healthcare providers. There is no such thing as a 'typical patient'. Different patients make different choices in different situations, determined by a

⁵ See results in Chapter 2

complex interplay of characteristics of patients and providers [45].

Another study showed that participation of patient organizations in formal decision-making, in order to empower them and democratize healthcare processes, is easier said than done. Patient organizations can participate in management processes but often have no influence on the important decisions about administrative subjects. Bottlenecks are the limited capacity, limited professional knowledge and limited representativeness of patient organizations [44].

The results of our study indicate that the majority of the public do not favour intensive or active methods of participation in regulation and therefore may not act as expected by policy makers. The majority of the public see others taking representative roles for them. This suggestion requires further research, which should include the public's and patient's perspectives.

Research into patients' participation in regulatory policies is still in its infancy. Nevertheless, the starting position should be that we do know the real purposes and added value of involving the public and patients in regulation. It should not be seen as a cure for all the problems regulators face. Including patients and their complaints, and responding effectively to them is one form, but many other forms can be considered. It is important to know what different forms of patient participation in regulation contribute to existing practices and to the various goals that are expected to be met by getting patients involved. Knowing that, it is also easier to determine in what form or mechanism patients and the public can be involved.

Research can then be carried out firstly into what forms of participations patients and the public prefer, and those forms could be evaluated in practice. The opinions and roles of inspectors should also be taken into account.

3. Dimension: regulation policies and strategies and their effects on quality of care

Theoretical assumptions underlying regulatory strategies

According to the theory of responsive regulation, strategies of regulation should be flexible, in synergy with the context of those being regulated, and based on dialogue. As described earlier, regulation based on trust will improve quality of care more effectively [18].

Single regulatory strategies are seldom effective [46]. The weaknesses of one strategy can be compensated by the strengths of another. A wide array of strategies such as monitoring performance indicators and targets, incident reporting systems, and stricter measures such as criminal penalties should together contribute to the effectiveness of regulation. Regulatory compliance is encouraged using cooperation, persuasion, inspection and enforcement notices in the first instance, and secondarily by applying heavier measures in the case of riskier behaviour. This principle is also known as the ‘stick-and-carrot’ approach [18, 46].

The Dutch Inspectorate as described determines its strategies using the theory of responsive regulation. The Inspectorate pays regular visits, which become more frequent if care providers do not comply with quality standards. Both care providers and the public can report incidents or lodge complaints. However, the Inspectorate’s statutory tasks mean that it is not responsible for handling individual complaints. It only investigates complaints when they are structural or very severe.

Information about the quality of care is collected and analysed to signal potential risks.

Information sources include the following:

- System-based supervision (monitoring of internal quality systems of care providers and governance arrangements)
- Performance indicators
- Reporting of incidents (by the public or care providers)
- Detection of prosecutable facts
- Thematic supervision

The Inspectorate is authorized to use the following regulation and enforcement instruments:

- Advice and incentives (consultation, campaigns)
- Corrective measures (imposing improvement plans, intensified monitoring)
- Administrative measures (command, advice to the Minister to issue a direction, penalty, administrative fine)
- Measures under criminal or disciplinary law

Results for the patient’s perspective on regulation policies and strategies

In order to understand better what the public’s expectations and ideas of what effective regulation policies and strategies are, we assessed public opinion with

regard to measures that the regulator should take in cases of poor healthcare quality, and what information sources should be used to monitor quality of care. We found differences and similarities between current policies and the ideas of the public.

The majority of the public indicated that the Inspectorate should firstly impose softer measures on care providers who fail to comply with quality standards, in the public's opinion.⁶ For instance, 96% indicated that the Inspectorate should double-check the care institution and 93% indicated that the Inspectorate should provide recommendations for improvements. This is in line with the regulator's current policies.

The same conclusions were found among patients with complaints when assessing what they expect after reporting their complaint. Particularly rigorous consequences for the care provider in question, such as sanctioning or banning from working, were less favoured by them when reporting their complaint. More important are the effects their complaints have on the healthcare system.⁷

The majority of the public support the use of complaints from patients, the general public and care providers for regulatory purposes. The majority (93%) indicated that the Inspectorate could rely most on complaints made by patients' associations. Fewer respondents (approximately half) agreed that the Inspectorate should rely on information provided by care institutions themselves, whereas this is the main source of information for many regulators.

Results in context of theory and other research

The majority of the public agree with the regulators' gradual approaches of imposing measures on care providers who fail to comply with quality standards, which is in line with the proposed 'stick-and-carrot' principle of the theory. Furthermore, the majority of the public seem to have little confidence in the internal monitoring of quality by care providers and the use of this information for regulation, while this is the principal information source regulators use.

These findings do not exactly reflect what was often argued in politics and the media: that society expects a stricter approach from the regulator in the case of incidents. Most of the public seem to have more nuanced opinions about what measures should be taken by a regulator. This also seems to depend on the situation, as research into risk as perceived by members of the public shows.

⁶ See results of Chapter 2

⁷ See results of chapters 3 and 6

Classical studies on the management of risks often state that our has society developed into a risk society over recent decades [47, 48]. It was thought that people overestimate risks and therefore require stricter government action. However, more recent studies have shown that the public are not risk-averse, but risk-realists: if they are well informed, they seem to accept risks to a certain extent and understand the responsibility of people themselves for risk prevention [42]. The majority of public are therefore realistic about what measures should be taken when things go wrong, but they see other information sources as more valuable for monitoring the quality of care. Relying on information collected by care providers alone could give a biased picture of the quality of care. The information could be complemented using other information sources more intensively, as proposed by the concept of 'tripartism' [24]. This could increase public confidence and accountability in healthcare and regulation.

Policy implications: using complaints for regulation

The majority of the public support the use of complaints for regulation; patients with complaints want their complaints to have an impact; and questions have been raised in several European countries about how patients' complaints should be valued and have a place in the regulatory process [2, 3, 5, 18, 24, 36, 37, 40]. The use of patients' complaints can be seen as a reduced form of tripartism whereby services become more responsive to and learn from their users.

Analyses of complaints on a larger scale is not common yet [12, 49, 50], especially not by regulators. In this respect, we investigated what value complaints could have for the regulation of healthcare quality. Driven by the results of the other studies, we aimed to develop standardization techniques for the analysis and utilization of patients' complaints for quality regulation at a higher level.⁸

Aggregated reporting on numbers of complaints could be a first step for using of complaints for various purposes. Internationally, researchers agree that aggregated analysis and reporting on adverse events (including complaints from patients) by care providers and regulators is required [49, 51-54], because this would lead to 'higher-level thinking and learning'; it would give a chance to proactively identify (system-wide) problem areas and quality and safety problems that point to poor care and risk areas [51, 54]. It could help regulators be accountable for their work and help make complaint evaluation procedures and decisions more homogenous and consistent. Furthermore, it could be a mechanism

⁸ See results in Chapter 4

for publicly showing what effects complaints have on the care system [50, 55-57].

Our aggregated analyses of complaints showed that it was indeed possible to identify problem areas and quality and safety issues.⁹ These types of detailed information could help give a more precise picture of what patients experience in various care sectors. The aggregated overview of complaints could be used for publicly reporting what effects complaints have on the healthcare system and informing the public about the regulators' work [49, 50, 58]. This could contribute positively to greater visibility of regulators; they are currently mostly only in the spotlight after incidents, and in a negative way. This could also help make evaluation procedures and decisions more homogenous and consistent, and improve public accountability.

However, we also found some restrictions on the use of complaints, especially for regulatory purposes.

The classification supports basic analyses, but does not accurately explain and map the complex reality behind a complaint. As the classification process reduces the complexity of the complaints, and excludes important details and background information, the information that the analysis provided remains rather superficial and makes it difficult to assess which complaints need regulatory action.

In addition, classification of complaints is effective from an organizational and professional perspective. But the complaints are classified within categories developed from a professional perspective, which may bias the real thoughts and feelings of patients.

However, without some form of standardized reporting of complaints, there is no way to monitor what patients experience in healthcare and give them a more consolidated voice in the regulatory practice. Furthermore, standardization of detailed complaint information could promote sharing between care providers, complaints boards and regulators, as well as encouraging learning processes.

There could be further assessment of whether aggregated analysis of complaints could be valuable for the regulation of healthcare. It would be possible to study whether future follow-up samples of complaints allow for comparisons over time that point out emerging problems experienced by patients. The predictive value of complaints could be studied further, for instance analysing the relationship between complaints and mortality rates, incidents, patient satisfaction, or regulatory measures against care providers.

⁹ See results in Chapter 5

It would also be possible to study what value complaints add to existing incident reporting systems. Furthermore, it is recommended that other information sources should be linked to the aggregated complaints data, such as incident reporting, risk management reports, patient complaints and malpractice claims. Whether patterns of non-reporting are detectable should be assessed. Moreover, integrative systems for achieving a detailed understanding of the full range of things that go wrong at the population level are largely undeveloped [54].

4. Dimension: expectations of individual patients when reporting their complaint to the Inspectorate

Policies on handling individual complaints by patients

There are differences between countries in what role patients' complaints currently have in healthcare quality regulation. In Finland for example, patients can file complaints with the healthcare quality regulator which then judges the legitimacy of the complaint [59, 60], while in other countries such as the UK and the Netherlands, individual complaint handling is not the primary task of the regulator. Signals derived from individual complaints are often used to monitor the performance of individual care providers [7, 12, 61]. As the responsibility for effective complaint handling is often given to the care providers, they often install specific complaints boards or bodies where patients can lodge their complaints [12, 53, 57, 62]. Other possibilities for patients to lodge their complaints are for instance disciplinary boards or ombudsmen [62].

In the Netherlands, it is possible for patients to register complaints about healthcare with the Inspectorate. The statutory tasks of the Inspectorate do not let it give individual judgements about complaints. Instead, it uses complaints for general risk analyses. Complaints are only eligible for handling by the Inspectorate and further investigation if they meet the following specific criteria: (i) severe deviation from the applicable professional standards by professional or other employees within the institution, (ii) severe failure or the absence of an internal quality system at an institution, (iii) severe harm to health or a high probability of recurrence of the problem [63]. If the complaint meets any of these criteria, the Inspectorate first asks the care provider in question to investigate the problem, in line with the theory of responsive regulation. If necessary, the Inspectorate starts its own investigation. If the complaint does not meet any of the criteria, the Inspectorate must ensure that the complainant receives information about other

options for obtaining a judgement [63, 64]. The Inspectorate receives approximately 1500 complaints from patients every year of which the majority are not handled by the Inspectorate, given its statutory task [64].

Results for patients' expectations when reporting their complaint to the regulator

Our study shows that patients with complaints have different perceptions than the regulators of how relevant their complaint is for healthcare quality. Three main dimensions became apparent in what patients with complaints expect from a regulator: expectations regarding consequences for the care provider in question, personal benefits and benefits for the quality of healthcare.¹⁰ Expectations regarding improving the quality of care were considered most important by respondents. Furthermore, personal benefits and consequences for the care provider were seen as less important.

Many patients regard their complaint as a structural problem or something that could happen again to others, expecting to improve the quality of care by reporting their complaint and feeling that things should change. However, most complaints are considered by the Inspectorate not to be structural or not severe enough to be eligible for further investigation.

The results of our studies also show that patients with complaints about organizational aspects felt less often that their complaint had an effect on quality of care.¹¹ This is obviously explained by the fact that fewer complaints about organizational issues were investigated further by the Inspectorate. However, patients believe those complaints are structural and think that there is also a learning potential from organizational problems for care providers and the regulator.

Results in the context of other research

When comparing different complaints procedures with different goals such as individual complainant satisfaction or disciplinary complaints procedures, complainants seem rather unanimous in what they expect of the procedures. For most people, it is important that their sense of justice is restored and that the problem is prevented from recurring [55-57, 65]. Aspects of procedural justice, such as diligence, impartiality, understanding and respect are also important to complainants. Research shows that those aspects are mostly well organized in most

¹⁰ See results in Chapter 3

¹¹ See results in Chapter 6

complaints procedures, including the Inspectorate's [39, 57]

It is not the Inspectorate's task to handle individual complaints. Patients who file a complaint with the Inspectorate seem to be aware of this, as evidenced by the low need expectations regarding personal satisfaction among patients who made complaints. They want to contribute to the quality of care. However, the majority of complainants believe that no changes are made in response to their complaint [57, 65, 66]. Patients' dissatisfaction with responses to their individual complaints is often associated with an expectation gap [50, 55-57]. Bismark (2015) argues that medico-legal agencies often focus too much on handling complaints in a procedurally correct way. This approach may have "dulled the senses", resulting in responses that are rather "pro forma" instead of focusing on meeting patients' expectations [53].

Implications for the Inspectorate

People seem to be aware of the task of the regulator. However, giving patients the possibility of reporting complaints also requires effective responses to them, including arranging the aspects of procedural justice. However, the results again stress the importance of recognizing that lay people have their own diverse interpretations of what their complaints mean for patient safety and these may conflict with current evaluation methods. The standardized procedures for responding and determining what complaints are structural or severe and the expectations and perceptions of patients about their complaints are not well aligned. Regulators should move away from traditional standardized procedures and favour more responsive, strategic and tailored approaches for responding to complainants. Patients' needs and expectations when reporting a complaint should be considered carefully, and they should be individually informed about the effects their complaints have on the healthcare system.

The expectations and experiences of patients from complaints procedures have been studied thoroughly over recent years and numerous efforts have been made to improve complaints procedures. However, learning from complaints (as is the case with incident reporting systems [67]) is lagging behind. Facilitating learning processes requires not only classifying and quantifying, but also social, participative and interactive processes at regulators and care providers. Regulators could pay more attention to how healthcare providers respond to complaints by patients and how they implement improvements indicated by complaints.

Methodological reflection

Strengths and limitations have already been described for each individual study. Only the most important ones will therefore be described here.

In addition to the general public, patients and their complaints were included in this study to gain more insight into the patients' perspective on healthcare quality. Patients with complaints actively express their experiences with healthcare. They are therefore relatively easy to track for research purposes.

Studying their expectations and experiences provided rich insights into what patients find important, their perspectives on healthcare quality, what they expect from a regulator and how they experienced the responses to their complaints. Studying complaints even gave us important insights into the regulator's perspective on healthcare quality. However, it must be stressed that patients with complaints tend to be female, somewhat older and better educated than average. This might be explained by the fact that this specific group feel more empowered to make their complaint to the regulator. In addition, females have shown to use healthcare more often than males in the Netherlands [68]. The results are therefore not representative of all patients or of the general public. They also cannot be directly translated to all other forms of patient participation. Furthermore, various studies have shown that different opinions were found within subgroups among the public, such as younger people or less well educated people. This should be taken into account when involving the public in regulation policies.

The response rate among patients with complaints in this study was modest, even after sending two reminders and a shortened questionnaire. The same applies to the response rates from the Dutch Consumer Panel. There is therefore a risk of response bias. Non-response analysis was not possible because no characteristics of the non-respondents are available, in part due to extensive privacy regulations. It was difficult to encourage people to fill out the questionnaire and increase the response rate.

Some respondents contacted us with questions about the study. Others indicated that completing the questionnaire made them uncomfortable because it revived the situation that the complaint was about. This could be an important reason for the non-response. Another reason could be that filing the complaint itself had already taken a lot of effort, making people reluctant to participate. Another observation is that respondents often chose the 'other' answer category and used the option of adding details about their complaint in open answer categories. This emphasizes the complexity and diversity of the complaints, which

are not easy to subdivide into standard categories.

Lastly, for the use of complaints for regulatory purposes in practice, it should be noted that receiving, classifying and recording complaints is a labour-intensive activity. A thorough examination is needed of which types of complaint information are coded. Furthermore, future analyses using the taxonomy require extensive rater preparation and practice. Rater preparation in content analysis is widely acknowledged to be an important condition for a valid assessment process [69].

Conclusions

This thesis provides more insights into what it would really mean if the Inspectorate truly wants to introduce the patients' and public's perspectives in its work. In addition to some concrete findings about the differences between the perspectives of patients and regulators on the four dimensions (quality of care, responsibilities, regulation strategies and expectations of individual patients with complaints), the main conclusion is that involving patients in regulation is a great challenge. It calls for fundamental changes and a paradigm shift on the regulator's side.

The current assessment frameworks and definitions of quality of healthcare that regulators use may not provide sufficient tools for incorporating the voice of patients in the practice of regulation. If regulators want to involve patients, it is important to pay more attention to organizational factors, relational aspects, and other 'softer' aspects of healthcare, as well as medical professional standards with regard to quality-of-care standards.

This means that the Inspectorate needs to work with another policy agenda, and it may require other regulation strategies. Furthermore, patients could be involved not only in the process of evaluating quality of care, but also in the development of regulation strategies and assessment frameworks.

However, the different perspectives of patients only stress the importance of listening to them carefully as this could prevent regulatory capture; it provides a more complete picture and broadens the horizons of inspectors. It could be difficult to bring into practice, but setting up continuous and non-sporadic public participation mechanisms and the long-term learning commitment of regulators are essential for good regulatory design.

A low profile, or only being visible during crises, contributes to the vulnerability of regulators. Reporting publicly about its work – not only on patients' complaints

but also on other subjects – could contribute to the Inspectorate’s visible profile and public accountability in a positive way, as well as reducing its vulnerability.

The ball is now in the Inspectorate’s court for the decision on how to proceed with the challenge of involving the public and patients more in its regulation policies.

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English summary

Introduction

Regulators in a number of countries have been criticized after high-profile incidents in healthcare. The criticisms often focus on their soft approach and on them ignoring patients' complaints. The regulators in various countries have therefore expressed a greater commitment to involving the public and patients more in their policies and improving responses to complaints. This is in line with broader international trends of democratization in healthcare.

This thesis provides insights into the perspectives of the public and patients, and into what it would mean if regulators involve the public and patients more in their work. This knowledge is needed for effectively aligning the regulators' and public's perspectives, and assessing different approaches to involving the public in regulation policies. Furthermore, the results of this thesis could help regulators respond more effectively to individual patients with complaints.

The studies were carried out in the Netherlands, where the Dutch Healthcare Inspectorate is responsible for healthcare quality regulation. In the studies, different populations were approached with various instruments in order to get a better more understanding of the public/ patient perspective and compare this to the regulator's perspective. The strategies of the studies, the study populations and the objectives are shown in the table below.

Objective	Strategy	Study population
Insights into opinions of the public on concepts of regulation¹	Question about general concepts of regulation	Respondents representative of the Dutch population
Understanding the expectations and experiences of people who submitted complaints to the Inspectorate²	Interviews and survey	People who reported a complaint to the Inspectorate
Perspectives of patients on quality of care and usefulness of complaints for regulation³	Development of taxonomy and content analyses	Content of complaints

¹ Chapter 2

² Chapters 3 and 6

³ Chapters 4 and 5

Main findings

The most important finding of this thesis is that there are differences between the perspectives of the public and patients versus that of the Inspectorate on four dimensions:

1. Quality of care
2. Responsibilities for healthcare quality
3. Regulation policies and strategies and their effects on quality of care
4. Expectations of individual patients when reporting their complaint to the Inspectorate

1. *The patients' perspectives on quality of care differ from the Inspectorate's perspective*

To analyse the patients' perspective on quality of care, we conducted content analyses on their complaints. In addition, we assessed which complaints were relevant according to the Inspectorate and were investigated further by them. Complaints with a clinical component were the subject of further investigations by the Inspectorate relatively much more often, whereas patients have other perceptions of quality of care. Their vision of quality of care is often based on a broader scope of aspects. As well as clinical aspects, organizational and relational aspects of care play a role. Another observation is that slight shifts of patterns were seen in the problems that patients reported between different healthcare sectors. For instance, patients in elderly care experience organizational problems more often, whereas in mental healthcare problems concerning patients' rights are more often encountered by patients.

The Dutch Inspectorate receives approximately 1500 complaints from patients each year of which the majority are not handled by the Inspectorate.

It is possible for patients to register complaints about healthcare with the Inspectorate. The statutory tasks of the Inspectorate do not let it give individual judgments about complaints. Complaints are only eligible for handling by the Inspectorate and further investigation if they point to a severe or structural problem. Other complaints bodies such as complaint officers at care providers are supposed to deal with individual complaints.

The differences in the perspectives of patients and the Inspectorate reflect what has often been discussed in other research: the differences between the 'biomedical' agenda of medico-legal agencies and the 'lifeworld' agendas of

patients. The medical model is often dominant and a leading determinant in constructing or reconstructing the context of medical harm, adverse events, complaints and regulating patient safety, while this does not always reflect how patients experienced it.

This raises the question of whether and how the Inspectorate will/can give the patients' perspective a place in its work.

The Dutch Healthcare Inspectorate monitors the quality of care using medical standards frameworks and professional guidelines. The patients' perspective is not always included in those guidelines and standards, and should be given a clearer place in the regulator's framework.

2. Patients see regulators as having most responsibility for quality

To assess how the public see the division of responsibilities for quality of care, we asked them how much the various parties involved, including the Dutch Inspectorate, are responsible in their opinion for quality of care. We included equivalent questions concerning quality regulation in the food service industry and in education, in order to assess whether public opinion is unique to the health sector or if it represents more common attitudes regarding responsibilities.

The Inspectorate was seen as having the most responsibility for quality of care by the general Dutch public, followed by the care providers, the minister, managers, colleagues of care providers, and finally the European Union. Patients were rated as bearing the least responsibility for quality of healthcare.

The same results were seen for quality of food and quality of education in this study: the public placed the regulators first with regard to responsibility for quality. Students and their parents in the educational setting and consumers in the food service industry were seen as the least responsible for quality in the sector.

The Inspectorate bases its policies on the theory of 'responsive regulation'. This theory is used by many regulators to design and develop their policies and strategies. The theory provides a basis for establishing how the relationship between regulator and regulated parties should be configured and how the regulator can determine what measures should be taken in cases of very poor quality of services. The basic idea of the theory is that the regulated parties are considered as trustworthy and intrinsically motivated by social responsibility. Strategies of regulation should be flexible, in synergy with the context of those being regulated, and based on dialogue. This vision is often described as 'high trust, high penalty'. Regulation based on distrust would lead to more sanctions, more

capacity requirements for the regulator and higher costs. Responsibility is therefore firstly laid at the regulated parties' door.

The results showed that the majority of the general Dutch public support the idea of 'high trust, high penalty' in the theory of responsive regulation, as a lot of responsibility was assigned to care providers. However, there is a generalized idea among the public that the state regulator has a prominent role.

An important component of the theory of responsive regulation is 'tripartism'. In tripartism, a public interest group such as a patients' or consumers' association participates as a third group in the regulatory process along with the regulator and the regulated party at the negotiation table that ensures enforcement and compliance.

It is assumed that giving the public a role can prevent regulatory capture, the effect in which there is a reduced distance between regulator and regulated party. The regulator is 'captured' by influence of the regulated party, and the public interest could be lost from sight. Consumer interests that are clear and articulable may provide relevant information and different perspectives that help counteract the regulated party's influence.

Furthermore, tripartism can be seen as a democratic way of giving patients and the public a voice in regulation. This is in line with broader developments of democratization in healthcare.

However, the studies show a kind of ambivalence among the public towards their own role in regulation of healthcare quality. This ambivalence is also seen in other research. When everything goes well and business is as usual, people do not expect much government interference. The public seem to endorse the principle of their own responsibility. But they choose government responsibility in concrete or 'risky' situations, when they are not well informed and/or when they are (emotionally) involved. For instance, people do want something to be done when incidents occur in healthcare.

The results indicate that the majority of the public do not favour intensive or active methods of participation in regulation. They see others taking representative roles for them, for instance patients' organizations. At the same time, patients' expectations of the role of regulators in the area of quality and safety are high.

3. The public support the regulator's soft approach

In order to gain a greater understanding about the public's expectations and ideas of what effective regulation policies and strategies are, we assessed the public's

opinions with regard to measures that the Inspectorate should take in cases of poor healthcare quality.

The majority of the public indicated that the Inspectorate should firstly impose softer measures on care providers who fail to comply with quality standards. The same conclusions were found among patients with complaints when assessing what they expect from reporting their complaint. Particularly rigorous consequences for the care provider in question, such as punishment or banning from working, were less favoured by them when reporting their complaint.

This is in line with the regulator's current policies based on the theory of responsive regulation. Single regulatory strategies are seldom effective, according to the theory. Weaknesses of one strategy can be complemented by strengths of another. A wide array of strategies such as monitoring performance indicators and targets, incident reporting systems, and stricter measures such as criminal penalties should together contribute to the effectiveness of regulation. Compliance is encouraged using cooperation, persuasion, inspection and enforcement notices in the first instance, and secondarily by applying heavier measures in the case of riskier behaviour. This principle is also known as the 'carrot-or-stick' approach.

In the Netherlands, care providers are expected to set up internal quality systems to monitor their own results quality of care. This information is also shared with the Inspectorate. The Inspectorate pays regular visits, which become more frequent if care providers do not comply with quality standards. Information about the quality of care is collected (e.g. using risk indicators and investigations of incidents) and analysed to signal potential risks.

We also asked the public's opinion about those information sources for monitoring quality of care. The majority of the public support the use of complaints by patients, members of the public and care providers for regulatory purposes. However, the majority of the public seem to have little confidence in the internal monitoring of quality by care providers and the use of this information for regulation, whereas this is in fact the dominant information source the Inspectorate uses.

4. Patients have other interpretations of the concept 'structural' than the Inspectorate

The results showed that there is a discrepancy between what individual patients expect from reporting their complaints and the policies of the Inspectorate. Many patients regard their complaint as a structural problem or something that could

happen again to others, while most complaints are considered by the Inspectorate not to be structural or severe enough to warrant further investigation. For many patients, this is difficult to understand.

It is not the Inspectorate's task to handle individual complaints. Patients who file a complaint with the Inspectorate seem to be aware of this, as evidenced by the low need expectations regarding personal satisfaction among patients who made complaints. However, if patients are given the possibility of reporting complaints, effective responses to them are also required.

Not only is a careful, respectful and impartial response needed, but the Inspectorate also needs to explain in understandable language why a complaint is not being investigated further. In addition, there could be active support to help patients find alternative options for lodging their complaints.

Individual complainants should be actively informed about what has been done with their complaint, both in cases where the Inspectorate has investigated the complaint and where it has not.

Conclusions

This thesis provides insights into the opinions of the public about regulation and what it would mean if the Inspectorate truly wants to introduce the patients' and public's perspectives in its work. In addition to a number of concrete findings about the differences between the perspectives of patients and regulators, the main conclusion is that involving patients in regulation is a great challenge. Their voice could act as a 'game changer' and a paradigm shift on the Inspectorate's side may therefore be needed. However, the different perspectives of patients only stress the importance of listening to them as this could prevent regulatory capture, as expressed in the concept of tripartism.

The current assessment frameworks and definitions of quality of healthcare that the Inspectorate uses may not provide sufficient tools to incorporate the voice of patients in the practice of regulation. It is important for the Inspectorate to pay more attention to organizational factors, relational aspects and other 'softer' aspects of healthcare, in addition to medical professional standards for quality of care. Patients and their representatives could be actively involved in those developments.

People who reported complaints to the Inspectorate feel they are a stakeholder in the process of improving healthcare quality and want to be involved. However, there is a difference between the interpretations that patients and the

inspectorate have of the term 'structural'. It is important that these two interpretations are brought into line with one another, in order to prevent frustration among patients. There should be greater clarity about how decisions are made about which complaints are investigated further. Lastly, patients should be individually informed about the effects their complaints have on the healthcare system.

Nederlandse samenvatting

Inleiding

In verschillende landen, waaronder Engeland, Australië, en Nederland, is er regelmatig forse kritiek op overheidstoezichthouders in de gezondheidszorg. De kritiek richt zich op hun 'zachte' aanpak bij incidenten en het negeren van klachten van patiënten. Toezichthouders willen patiënten daarom een grotere rol geven in hun beleid. Zo ook de Inspectie voor de Gezondheidszorg (IGZ) in Nederland. De Inspectie is verantwoordelijk voor het toezicht op de kwaliteit van de Nederlandse gezondheidszorg.

Onder andere de Nationale Ombudsman heeft kritiek geleverd op de Inspectie en bepleit dat de Inspectie meer rekening moet houden met het burger- en patiëntenperspectief. Net als in het vorige Meerjarenbeleidsplan geeft de Inspectie daarom in haar nieuwste Meerjarenbeleidsplan 2016-2019 de patiënt een belangrijke rol in het toezicht. De Inspectie wil patiënten en hun naasten intensiever betrekken bij het toezicht en mede vanuit hun perspectief een oordeel vormen over de kwaliteit en veiligheid van de zorg.

Dit proefschrift geeft inzicht in het burger- en patiëntenperspectief op toezicht en kwaliteit van zorg en de consequenties van het betrekken van patiënten bij het toezicht. Doel van het onderzoek is een bijdrage te leveren aan een goede afstemming tussen de perspectieven van toezichthouders en burgers. Op basis van onderzoek onder burgers en patiënten, en onderzoek naar de manier waarop de Inspectie in Nederland klachten van burgers behandelt, is inzicht verkregen in het perspectief van patiënten en burgers op toezicht en kwaliteit van zorg.

Deze kennis kan bijdragen aan het effectief betrekken van patiënten bij het werk van de Inspectie en aan de manier waarop de Inspectie met patiënten en hun klachten omgaat. De aanpak van dit onderzoek, studiepopulaties en onderzoeksdoelen staan weergegeven in onderstaande tabel.

Doel	Aanpak	Onderzoekspopulatie
Inzicht in visie van burgers op algemene toezichtskoncepten¹	Vragen over toezichtskoncepten	Respondenten representatief voor de Nederlandse bevolking naar geslacht en leeftijd
Verwachtingen en ervaringen van burgers met de Inspectie²	Interviews en vragenlijst	Personen die een klacht hebben gemeld bij de Inspectie
Perspectief van patiënten op kwaliteit van zorg en bruikbaarheid klachten voor toezicht³	Ontwikkeling taxonomie en inhoudelijke analyses	Inhoud van klachten

Bevindingen

Uit onze deelstudies komt naar voren dat de perspectieven van patiënten en burgers verschillen met die van de Inspectie. Deze verschillen uit zich op vier dimensies:

1. Kwaliteit van zorg
2. Verantwoordelijkheden voor kwaliteit van zorg
3. Strategieën van toezicht en de effecten daarvan op kwaliteit van zorg
4. Verwachtingen van individuele patiënten bij het melden van hun klacht bij de Inspectie

1. Het patiëntenperspectief op kwaliteit van zorg verschilt van die van de Inspectie

Om het patiëntenperspectief op kwaliteit van zorg in kaart te brengen hebben we klachten van patiënten inhoudelijk geanalyseerd. Daarnaast hebben we onderzocht welke klachten als relevant werden geacht en nader onderzocht zijn door de Inspectie.

Voor de Inspectie blijken vooral klachten over klinische aspecten relevant bij het beoordelen van de kwaliteit van zorg, terwijl patiënten andere percepties hebben van kwaliteit van zorg. Hun beeld van de zorg is vaak gebaseerd op een breder scala

¹ Hoofdstuk 2

² Hoofdstuk 3 en 6

³ Hoofdstuk 4 en 5

aan verschillende factoren. Naast de klinische aspecten spelen ook organisatorische factoren en het contact met de zorgverlener een rol. Ook zagen we verschillen tussen zorgsectoren in de onderwerpen die patiënten bij de Inspectie aandragen. Zo ervaren patiënten in de verpleging en verzorging vaker organisatorische problemen, en komen in de geestelijke gezondheidszorg vaker problemen omtrent patiëntenrechten voor.

De Inspectie ontvangt jaarlijks zo'n 1500 meldingen van klachten door burgers. Het merendeel wordt niet door de Inspectie onderzocht waarbij de klager wordt geadviseerd de klacht elders in te dienen. Burgers kunnen klachten melden bij de Inspectie, maar de Inspectie is niet verantwoordelijk voor individuele klachtbehandeling. De verantwoordelijkheid hiervoor ligt primair bij de zorginstellingen. Daarnaast hebben patiënten de mogelijkheid een tuchtklacht in te dienen of een beroep te doen op een geschilleninstantie of het civielrecht. De Inspectie onderzoekt meldingen van burgers alleen wanneer die wijzen op een structureel of ernstig probleem bij de zorgaanbieder.

De verschillen in perspectieven die wij vonden sluiten aan bij eerder onderzoek: de mismatch tussen de 'biomedische agenda' van gezondheidssystemen en -instituten en de 'leefwereld' van patiënten. Het medische model speelt een dominante rol bij het reconstrueren en beoordelen van medisch vermijdbare schade, klachten en patiëntveiligheid en -kwaliteit door inspecteurs. Dit sluit maar gedeeltelijk aan bij de opvattingen van patiënten.

Dit roept de vraag op of en op welke manier de Inspectie dit patiëntenperspectief een plek wil/kan geven in haar toezicht.

De Inspectie houdt toezicht op kwaliteit van zorg door professionele standaarden en normenkaders van het veld, het perspectief van de patiënt is hierin niet altijd meegenomen. Als de Inspectie de patiënt meer wil betrekken bij het toezicht zijn de huidige professionele normen niet toereikend en moet het perspectief van de patiënten een duidelijkere plaats krijgen in het normenkader.

2. Patiënten zien de Inspectie als meest verantwoordelijk voor kwaliteit van zorg

Om te onderzoeken wat de visie is van burgers over de verdeling van verantwoordelijkheden voor kwaliteit van zorg, hebben we hen gevraagd in hoeverre verschillende actoren, waaronder de Inspectie, naar hun mening verantwoordelijkheid dragen voor kwaliteit van de gezondheidszorg. Om dit in perspectief te kunnen plaatsen is hetzelfde gevraagd voor de Voedsel en

Warenautoriteit (VWA) op het gebied van voedsel en de Onderwijsinspectie op het gebied van onderwijs.

De Inspectie werd als meest verantwoordelijk gezien voor kwaliteit van zorg. Daarna kwamen de zorgaanbieders, de Minister, managers, collega's van zorgverleners en de Europese Unie. Patiënten werden als minst verantwoordelijk gezien. Dezelfde patronen werden gezien in de voedsel- en onderwijssector: de toezichthouders werden de meeste verantwoordelijkheid toebedeeld en leerlingen en consumenten de minste.

De Inspectie baseert haar beleid op de theorie van 'responsive regulation'. Deze theorie wordt door toezichthouders gebruikt voor de ontwikkeling van hun beleid en strategieën. De theorie geeft een onderbouwing voor de inrichting van de relatie tussen toezichthouder en ondertoezichtstaanden en de bepaling van welke maatregelen moeten worden genomen door toezichthouders in geval van slechte kwaliteit. Het idee achter deze strategie is dat het merendeel van de ondertoezichtstaanden te vertrouwen is en intrinsiek gemotiveerd is om het goede te doen en te handelen in het belang van de burgers/gebruikers. Kwaliteit van de dienstverlening is de verantwoordelijkheid van de aanbieders, die dat in veel gevallen ook waarmaken. Wantrouwen ondermijnt de professionele motivatie en verantwoordelijkheid en brengt hoge toezichtslasten met zich mee. Volgens de theorie van responsive regulation, zijn toezichtsstrategieën flexibel en gebaseerd op dialoog met de ondertoezichtstaanden. Deze visie wordt vaak omschreven als 'high trust, high penalty'.

Burgers lijken achter het idee van 'high trust, high penalty' te staan omdat ze zorgaanbieders ook een hoge mate van verantwoordelijkheid toebedelen. Maar ze zien wel een grotere rol voor de toezichthouder.

Een ander belangrijk element in de theorie van responsive regulation is 'tripartisme'. Het idee achter tripartisme is dat een derde groep die de belangen van burgers behartigt aansluit bij het onderhandelingsproces tussen toezichthouder en ondertoezichtstaande, bijvoorbeeld een groep patiënten of consumenten.

Tripartisme zou 'capture' (inkapseling) kunnen voorkomen. Bij 'capture' is er sprake van een verminderde afstand tussen toezichthouder en ondertoezichtstaande, waarbij de toezichthouder teveel beïnvloed wordt door de ondertoezichtstaande en daarbij het publieke belang uit het oog dreigt te verliezen. Bovendien kan door tripartisme het belang en het perspectief van de consument worden ingebracht in het toezicht. Tripartisme is een democratisch mechanisme

om burgers een stem te geven in toezicht. Dit past bij de bredere ontwikkelingen van democratisering in de zorg.

Burgers staan echter ambivalent tegenover hun eigen rol bij het toezicht. Zij zien voor zichzelf in de meeste gevallen geen primaire rol, maar verwachten eerder een bijdrage van een patiëntenorganisatie. Deze ambivalentie is vaker geobserveerd in ander onderzoek.

Als alles gaat zoals gewoonlijk, 'business as usual', verwachten mensen niet teveel bemoeizucht vanuit de overheid. Ook onderschrijven mensen de principes van 'eigen verantwoordelijkheid' van burgers. Maar wanneer er concreet iets misgaat, en wanneer mensen niet goed geïnformeerd zijn of emotioneel betrokken zijn, kiezen ze voor een grote rol van de overheid. Men wil bijvoorbeeld wel dat er wordt opgetreden wanneer er iets fout gaat in de zorg.

De resultaten van ons onderzoek geven aan dat de meerderheid van de burgers niet de voorkeur geeft aan intensieve of actieve vormen van participatie in het toezicht. Tegelijk zijn de verwachtingen van patiënten over de rol die de Inspectie speelt op het terrein van kwaliteit en veiligheid hooggespannen.

3. Burgers en patiënten onderschrijven een zachte aanpak door de Inspectie

Om te begrijpen hoe burgers aankijken tegen verschillende toezichtsinterventies hebben we hen gevraagd wat er volgens hen voor maatregelen genomen moeten worden in gevallen van slechte kwaliteit van zorg.

Het merendeel van de burgers gaf de voorkeur aan het inzetten van zachtere maatregelen, zoals advies of extra controleren van zorgverleners. Patiënten met een klacht deelden deze visie: men had de voorkeur voor het opleggen van zachtere maatregelen door de Inspectie, zoals een gesprek aangaan met de zorgverlener, in plaats van hardere, zoals het straffen van de zorgverlener. Dit sluit aan bij het beleid van de Inspectie gebaseerd op de theorie van 'responsive regulation'.

Combinaties van verschillende toezichtsinterventies zijn volgens deze theorie het meest effectief. Zwakke punten van één interventie kunnen worden aangevuld met sterke punten van een andere. Een breed scala aan interventies zoals het monitoren van prestatie-indicatoren, incident meldingssystemen, adviseren, stimuleren en bestuursrechtelijke en strafrechtelijke sancties dragen gezamenlijk bij aan de effectiviteit van het toezicht. Naleving van de regelgeving wordt in eerste instantie aangemoedigd door het gebruik van 'zachte' maatregelen als samenwerking, advies en overtuiging, en in tweede instantie door het toepassen

van zwaardere maatregelen. Dit principe is ook bekend als ‘the stick or the carrot’. In Nederland worden zorgaanbieders geacht kwaliteitssystemen op te zetten waarbij zij hun eigen resultaten op kwaliteit monitoren. Deze informatie wordt ook aan de Inspectie geleverd. Er wordt op verschillende manieren informatie verzameld en geanalyseerd over kwaliteit van zorg, bijvoorbeeld door middel van risico indicatoren, en onderzoek naar meldingen van incidenten en calamiteiten door zorgaanbieders en burgers. Wanneer de kwaliteit van zorg niet op orde is, intensificeert de Inspectie het toezicht op de zorgaanbieder.

Over deze informatieverzameling door de Inspectie hebben wij burgers ook hun mening gevraagd. Burgers moedigen het gebruik door het toezicht van informatie uit klachten van zowel zorgaanbieders, als burgers en patiëntenorganisaties aan. Minder vertrouwen heeft men in informatie verzameld door zorgaanbieders zelf, terwijl dit momenteel wel de meest gebruikte informatiebron van de Inspectie is.

Burgers zijn het dus eens met de zachte aanpak van de Inspectie, maar hebben andere ideeën over de informatiebronnen voor het gebruik van toezicht.

4. Patiënten hebben een andere interpretatie van het begrip structureel dan de Inspectie

Onze studies laten zien dat er een discrepantie bestaat tussen wat klagers willen bereiken door hun klacht te melden en het beleid van de Inspectie. Veel patiënten zien hun klacht als een structureel probleem van een zorgaanbieder dat andere patiënten ook kan raken, terwijl de Inspectie de meeste klachten niet als structureel ziet en ze dus niet in behandeling neemt. Veel patiënten vonden dit lastig te begrijpen.

Patiënten lijken zich er wel bewust van te zijn dat de Inspectie geen individueel klachtbehandelaar is. Ze melden zich ook niet bij de Inspectie om persoonlijke genoegdoening te krijgen. Maar, alsnog is het belangrijk dat er effectief wordt gereageerd wanneer patiënten hun klacht melden. Niet alleen moet er op een zorgvuldige, respect- en begripvolle en onpartijdige manier gereageerd worden, maar er kan ook door de Inspectie worden uitgelegd waarom een klacht niet wordt onderzocht in een voor de klager begrijpelijke taal. Daarnaast kan de klager actief geholpen worden bij het zoeken van alternatieven voor het indienen van een klacht.

Individuele klagers kunnen actief geïnformeerd worden over wat er met hun klacht is gedaan, zowel in gevallen waarbij geen of juist wel onderzoek is gedaan door de Inspectie.

Conclusie

Dit proefschrift geeft meer inzicht in de opvattingen van burgers over het toezicht en wat er moet gebeuren om het patiëntenperspectief daadwerkelijk in het werk van de Inspectie te introduceren. Naast een aantal concrete bevindingen over de verschillen tussen de perspectieven van patiënten en toezichthouders is de belangrijkste conclusie dat het betrekken van patiënten bij het toezicht een grote uitdaging is. Het inbrengen van het patiëntenperspectief kan fungeren als een 'game changer'. Het vraagt om een paradigmaverschuiving bij de Inspectie; bestaande werkwijzen en concepten komen in een nieuw licht te staan. Ondanks dat dit niet makkelijk zal zijn, benadrukken de verschillende perspectieven van patiënten het belang om naar hen te luisteren. Dit kan 'capture' voorkomen zoals voorgesteld met het 'tripartisme', en verbreedt het inspectieperspectief.

De huidige toetsingskaders en definities van kwaliteit van de gezondheidszorg die de IGZ gebruikt, en de huidige praktijk, bieden niet genoeg handvatten om de stem van de patiënten door te laten klinken. Het is voor de Inspectie van belang om meer aandacht te besteden aan organisatorische factoren, relationele aspecten, en andere aspecten van de gezondheidszorg, naast de medisch professionele normen. Patiënten en hun vertegenwoordigers kunnen bij deze ontwikkelingen actief betrokken worden.

Patiënten die klachten melden voelen zich betrokken bij het proces van kwaliteitsverbetering in de zorg. Er is echter een verschil tussen hoe patiënten tegen het begrip 'structureel' aankijken en hoe de Inspectie hier tegenaan kijkt. Het is belangrijk dat deze twee perspectieven op elkaar worden afgestemd, om teleurstelling onder melders te voorkomen. Dit is geen eenzijdig proces: het is belangrijk dat de Inspectie in gesprek gaat met patiënten om ook beter aan te sluiten bij de definitie die patiënten geven aan het begrip 'structureel'. Ook kan meer duidelijkheid worden gegeven over hoe besluitvorming over het al dan niet in behandeling nemen van meldingen plaatsvindt. Tot slot wordt aangeraden om patiënten die klachten melden bij de Inspectie te informeren over het effect van hun klachten op de kwaliteit van zorg.

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Curriculum Vitae

Renée Bouwman was born on September 6, 1986 in Kingston, Jamaica. She grew up in Wageningen and finished secondary school at Pantarijn. After that, she studied the bachelor and master Health Sciences (specialization Policy and Organization of Health Care) at VU University in Amsterdam, the Netherlands. Her internship on the utilization of research among policy makers was performed at the National Institute for Public Health and the Environment (RIVM). After her cum laude graduation in 2011, she started working at the Netherlands Institute for Health Services Research (NIVEL). She worked on differing research projects concerning patients' rights and perspectives, regulation of quality of care, and organ donation and transplantation. From 2012-2016, she worked on her PhD under supervision of Roland Friele, Paul Robben and Manja Bomhoff. She will continue working as a postdoc researcher at NIVEL on projects regarding organ donation and transplantation, involving patients and their families in incident investigation, experiences of doctors with disciplinary law, and regulation of quality of youth care.

